Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Dog Ear Scars From Mastectomy	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Explanted Due To Right Side Being Removed	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	False Positive For Rupture On Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Inframammay Fold Too High	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lack Of Projection	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Mondor's Disease	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Muscle Spasm	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Complications	3 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Related Unplanned	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pt Requests Removal Due To Personal Reasons	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Siliconoma	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-36 Months	Soft Mass Left Costal Margin	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Symmastia	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	0 (0.0)	0 (0 0)	2 (100.0)	0 (0.0)	2 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Wide Scars	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	274 (44.8)	60 (9.8)	179 (29.2)	92 (15.0)	7 (1.1)	612 (100.0)
	II. Cosmetic Complication						
	Asymmetry	10 (40.0)	2 (8.0)	6 (24.0)	7 (28.0)	0 (0.0)	25 (100.0)
	Hypertrophic Scarring	72 (80.0)	0 (0.0)	7 (7.8)	11 (12.2)	0 (0.0)	90 (100.0)
	Ptosis	5 (11.9)	0 (0.0)	11 (26.2)	26 (61.9)	0 (0.0)	42 (100.0)
	Wrinkling	4 (20.0)	7 (35.0)	8 (40.0)	1 (5.0)	0 (0.0)	20 (100.0)
	Any Cosmetic Complication	91 (51.4)	9 (5.1)	32 (18.1)	45 (25.4)	0 (0.0)	177 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08.48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Total Number Complications	225 (59.8)	32 (8.5)	69 (18.4)	50 (13.3)	0 (0.0)	376 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	13 (23.2)	18 (32.1)	19 (33.9)	6 (10.7)	0 (0.0)	56 (100.0)
	Baker III, IV Capsular Contracture	15 (23.4)	23 (35.9)	20 (31.3)	6 (9.4)	0 (0.0)	64 (100.0)
	Baker IV Capsular Contracture	2 (25.0)	5 (62.5)	1 (12.5)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	3 (50.0)	3 (50.0)	0 (0.0)	6 (100.0)
	Breast Pain	11 (78.6)	0 (0.0)	2 (14.3)	1 (7.1)	0 (0.0)	14 (100.0)
	Breast Sensation Changes	13 (92.9)	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)	14 (100.0)
	Delayed Wound Healing	6 (75.0)	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	8 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)	0 (0.0)	5 (100.0)
	Extrusion	3 (75.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Granuloma	0 (0.0)	0 (0.0)	1 (33.3)	2 (66.7)	0 (0.0)	3 (100.0)
	Hematoma	12 (60.0)	0 (0.0)	2 (10.0)	6 (30.0)	0 (0.0)	20 (100.0)
	Implant Malposition/Displacement	4 (57.1)	1 (14.3)	2 (28.6)	0 (0.0)	0 (0.0)	7 (100.0)
	Infection	10 (50.0)	0 (0.0)	8 (40.0)	2 (10.0)	0 (0.0)	20 (100.0)
	Inflammation	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Lymphadenopathy	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Necrosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Nipple Sensation Changes	61 (93.8)	0 (0.0)	3 (4.6)	1 (1.5)	0 (0.0)	65 (100.0)
	Placement Damage	1 (25.0)	2 (50.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Rash	7 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Seroma	22 (91.7)	0 (0.0)	1 (4.2)	1 (4.2)	0 (0.0)	24 (100.0)
	Suture Reaction	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Other	15 (60.0)	1 (4.0)	3 (12.0)	6 (24.0)	0 (0.0)	25 (100.0)
	Capsular Contracture Secondary To Radiation Therapy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Capsule Tear	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Cellulitis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Deep Vein Thrombosis	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Dog Ear Scars From Mastectomy	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Ecchymosis	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Excessive Implant Movements	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Extra Skin	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Implants Riding High	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Loss Of Inframammary Fold	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Mondor's Disease	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
0-6 Months	Muscle Spasm	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Pain - Sternum And Under Left Arm Intermittent	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Symmastia And Implant Malposition	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Wide Scars	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	185 (60.9)	27 (8.9)	52 (17.1)	40 (13.2)	0 (0.0)	304 (100.0)
	II. Cosmetic Complication						
	Asymmetry	4 (33.3)	2 (16.7)	2 (16.7)	4 (33.3)	0 (0.0)	12 (100.0)
	Hypertrophic Scarring	32 (82.1)	0 (0.0)	6 (15.4)	1 (2.6)	0 (0.0)	39 (100.0)
	Ptosis	2 (22.2)	0 (0.0)	2 (22.2)	5 (55.6)	0 (0.0)	9 (100.0)
	Wrinkling	2 (16.7)	3 (25.0)	7 (58.3)	0 (0.0)	0 (0.0)	12 (100.0)
	Any Cosmetic Complication	40 (55.6)	5 (6.9)	17 (23.6)	10 (13.9)	0 (0.0)	72 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Total Number Complications	53 (34.2)	14 (9.0)	58 (37.4)	30 (19.4)	0 (0.0)	155 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	4 (10.3)	10 (25.6)	23 (59.0)	2 (5.1)	0 (0.0)	39 (100.0)
	Baker III, IV Capsular Contracture	5 (11.1)	11 (24.4)	26 (57.8)	3 (6.7)	0 (0.0)	45 (100.0)
	Baker IV Capsular Contracture	1 (16.7)	1 (16.7)	3 (50.0)	1 (16.7)	0 (0.0)	6 (100.0)
	Breast Mass	1 (14.3)	0 (0.0)	4 (57.1)	2 (28.6)	0 (0.0)	7 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Breast Sensation Changes	3 (50.0)	0 (0.0)	3 (50.0)	0 (0.0)	0 (0.0)	6 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Extrusion	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Hematoma	1 (50.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Implant Malposition/Displacement	0 (0.0)	1 (33.3)	1 (33.3)	1 (33.3)	0 (0.0)	3 (100.0)
	Infection	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Inflammation	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	1 (20.0)	4 (80.0)	0 (0.0)	5 (100.0)
	New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	0 (0.0)	1 (33.3)	2 (66.7)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	24 (82.8)	0 (0.0)	3 (10.3)	2 (6.9)	0 (0.0)	29 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Other	3 (30.0)	0 (0.0)	6 (60.0)	1 (10.0)	0 (0.0)	10 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS
Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
6-12 Months	Back And Neck Pain Related To Large Implants	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Distortion Of Breast Shape Not Related To Capsular Contracture	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Muscle Spasm	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Pt Requests Removal Due To Personal Reasons	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Symmastia	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Tight Benilli Suture	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	38 (31.1)	12 (9.8)	52 (42.6)	20 (16.4)	0 (0.0)	122 (100.0)
	II. Cosmetic Complication						
	Asymmetry	0 (0.0)	0 (0.0)	4 (80.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	15 (68.2)	0 (0.0)	0 (0.0)	7 (31.8)	0 (0.0)	22 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	1 (33.3)	2 (66.7)	0 (0.0)	3 (100.0)
	Wrinkling	0 (0.0)	2 (66.7)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Any Cosmetic Complication	15 (45.5)	2 (6.1)	6 (18.2)	10 (30.3)	0 (0.0)	33 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Total Number Complications	66 (37.5)	16 (9.1)	57 (32.4)	32 (18.2)	5 (2.8)	176 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	10 (30.3)	7 (21.2)	13 (39.4)	3 (9.1)	0 (0.0)	33 (100.0)
	Baker III, IV Capsular Contracture	11 (27.5)	13 (32.5)	13 (32.5)	3 (7.5)	0 (0.0)	40 (100.0)
	Baker IV Capsular Contracture	1 (14.3)	6 (85.7)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	10 (71.4)	4 (28.6)	0 (0.0)	14 (100.0)
	Breast Pain	0 (0.0)	0 (0.0)	8 (100.0)	0 (0.0)	0 (0.0)	8 (100.0)
	Breast Sensation Changes	3 (75.0)	0 (0.0)	1 (25.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Hematoma	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Implant Malposition/Displacement	2 (66.7)	0 (0.0)	1 (33.3)	0 (0.0)	0 (0.0)	3 (100.0)
	Infection	1 (25.0)	0 (0.0)	3 (75.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Lactation Difficulties	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	1 (33.3)	2 (66.7)	0 (0.0)	3 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	New Diagnosis of Rheumatic Disease	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	14 (87.5)	0 (0.0)	2 (12.5)	0 (0.0)	0 (0.0)	16 (100.0)
	Rash	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)	5 (100.0)
	Seroma	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
12-24 Months	Other	3 (25.0)	1 (8.3)	5 (41.7)	3 (25.0)	0 (0.0)	12 (100.0)
	Abnormal Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Anaphylaxis	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Inframammay Fold Too High	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lack Of Projection	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Nipple Complications	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)
	Nipple Related Unplanned	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Numbness In Both Hands At Night	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Skin Lesion	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Soft Mass Left Costal Margin	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Surgical Removal Of Ectopic Pregnancy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	36 (29.3)	14 (11.4)	52 (42.3)	16 (13.0)	5 (4.1)	123 (100.0)
	II. Cosmetic Complication						
	Asymmetry	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Hypertrophic Scarring	23 (88.5)	0 (0.0)	1 (3.8)	2 (7.7)	0 (0.0)	26 (100.0)
	Ptosis	3 (15.0)	0 (0.0)	4 (20.0)	13 (65.0)	0 (0.0)	20 (100.0)
	Wrinkling	2 (50.0)	2 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (100.0)
	Any Cosmetic Complication	30 (56.6)	2 (3.8)	5 (9.4)	16 (30.2)	0 (0.0)	53 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

· Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5 3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality: Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Total Number Complications	21 (25.6)	7 (8.5)	27 (32.9)	25 (30.5)	2 (2.4)	82 (100.0)
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	5 (50.0)	3 (30.0)	2 (20.0)	0 (0.0)	0 (0.0)	10 (100.0)
	Baker III, IV Capsular Contracture	5 (33.3)	5 (33 3)	5 (33.3)	0 (0.0)	0 (0.0)	15 (100.0)
	Baker IV Capsular Contracture	0 (0.0)	2 (40.0)	3 (60.0)	0 (0.0)	0 (0.0)	5 (100.0)
	Breast Mass	0 (0.0)	0 (0.0)	5 (71.4)	2 (28.6)	0 (0.0)	7 (100.0)
	Breast Sensation Changes	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	External Injury Not Related To Breast Implants	0 (0.0)	0 (0.0)	0 (0.0)	3 (100.0)	0 (0.0)	3 (100.0)
	Lactation Difficulties	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Metastatic Disease	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	Miscarriage	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Necrosis	1 (33.3)	0 (0.0)	0 (0.0)	2 (66.7)	0 (0.0)	3 (100.0)
	Nipple Sensation Changes	6 (35.3)	0 (0.0)	9 (52.9)	1 (5.9)	1 (5.9)	17 (100.0)
	Rupture	0 (0.0)	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	3 (100.0)
	Other	1 (11.1)	0 (0.0)	4 (44.4)	4 (44.4)	0 (0.0)	9 (100.0)
	Deep Vein Thrombosis	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Explanted Due To Right Side Being Removed	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	2 (100.0)
	False Positive For Rupture On Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Occasional Burning Discomfort Of Skin.	0 (0.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0 0)	2 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.5.3

POSTOPERATIVE COMPLICATIONS BY CAUSALITY (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Causality					
		Procedure Related n (%)	Device Related n (%)	Unknown n (%)	Other n (%)	Missing n (%)	Total (a) n (100%)
24-36 Months	Positive Antinuclear Antibodies Negative For Lupus	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Siliconoma	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Stitch Abscess	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Any Complication Excluding Cosmetic	15 (23.8)	7 (11.1)	23 (36.5)	16 (25.4)	2 (3.2)	63 (100.0)
	II. Cosmetic Complication						
	Asymmetry	4 (80.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	5 (100.0)
	Hypertrophic Scarring	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	3 (100.0)
	Ptosis	0 (0.0)	0 (0.0)	4 (40.0)	6 (60.0)	0 (0.0)	10 (100.0)
	Wrinkling	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Any Cosmetic Complication	6 (31.6)	0 (0.0)	4 (21.1)	9 (47.4)	0 (0.0)	19 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_53.SAS Creation Date, Time: 24AUG04 08:48

Note 1. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, low/high sensitivity, nipple complications, and wrinkling.

(a) Percentages are based upon the total number of complications, or the total number of occurrences within any non-cosmetic, any cosmetic, or each specific complication, as appropriate.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Total Number of Complications	246	202.9	118.5	231.21	1	1090
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	45	268.7	199.0	231.80	8	939
	Baker III, IV Capsular Contracture	53	247.8	178.0	221.92	8	939
	Baker IV Capsular Contracture	8	130.5	88.0	97.91	54	302
	Breast Mass	6	51.2	51.5	48.88	1	135
	Breast Pain	11	125.8	31.0	179.97	6	506
	Breast Sensation Changes	9	572.9	681.0	379.43	79	1090
	External Injury Not Related To Breast Implants	5	41.6	50.0	22.90	15	71
	Granuloma	1	12.0	12.0		12	12
	Hematoma	15	8.3	2.0	13.56	1	46
	Implant Malposition/Displacement	1	23.0	23.0		23	23
	Infection	9	78.4	46.0	70.27	4	194
	Inflammation	2	73.0	73.0	43.84	42	104
	Lymphadenopathy	1	8.0	8.0		8	8
	Miscarriage	5	25.2	2.0	32.75	1	64
	Necrosis	2	14.0	14.0	4.24	11	17
	Nipple Sensation Changes	51	332.0	338.0	214.87	32	777
	Placement Damage	4	1.0	1.0	0.00	1	1
	Rash	4	18.0	15.0	7.39	13	29
	Seroma	6	19.7	6.0	26.90	1	67
	Suture Reaction	4	91.3	94.0	55.32	38	139
	Other	13	103.2	57.0	168.20	1	628

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Distortion Of Breast Shape Not Related To Capsular Contracture	1	628.0	628.0		628	628
	Ecchymosis	2	57.0	57.0	0.00	57	57
	Explanted Due To Right Side Being Removed	2	1.0	1.0	0.00	1	1
	Implants Riding High	2	176.0	176.0	0.00	176	176
	Mondor's Disease	3	24.0	13.0	19.05	13	46
	Pt Requests Removal Due To Personal Reasons	2	79.0	79.0	0.00	79	79
	Soft Mass Left Costal Margin	1	16.0	16.0		16	16
	Any Complication Excluding Cosmetic	202	199.0	102.5	234.33	1	1090
	II. Cosmetic Complication						
	Asymmetry	2	208.5	208.5	149.20	103	314
	Hypertrophic Scarring	29	252.5	161.0	236.66	1	1011
	Ptosis	8	141.4	81.5	123.75	50	336
	Wrinkling	5	167.4	82.0	250.45	30	613
	Any Cosmetic Complication	44	220 6	132.0	217.96	1	1011

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08.48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Total Number of Complications	141	210.7	103.0	260.40	1	1090
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	21	213.4	142.0	226.86	16	939
	Baker III, IV Capsular Contracture	21	213.4	142.0	226.86	16	939
	Breast Mass	1	49.0	49.0		49	49
	Breast Pain	7	97.9	31.0	180.35	6	506
	Breast Sensation Changes	7	714.0	701.0	295.67	357	1090
	External Injury Not Related To Breast Implants	3	40 7	50.0	16.17	22	50
	Granuloma	1	12.0	12.0		12	12
	Hematoma	12	7.8	1.0	14.92	1	46
	Infection	9	78.4	46.0	70.27	4	194
	Inflammation	2	73.0	73.0	43.84	42	104
	Lymphadenopathy	1	8.0	8.0		8	8
	Miscarriage	1	2.0	2 0		2	2
	Nipple Sensation Changes	30	398.2	363.5	242.25	32	777
	Placement Damage	4	1.0	1.0	0.00	1	1
	Rash	4	18.0	15.0	7.39	13	29
	Seroma	6	19.7	6.0	26.90	1	67
	Suture Reaction	4	91.3	94.0	55.32	38	139
	Other	8	145.8	57.0	205.41	13	628
	Distortion Of Breast Shape Not Related To Capsular Contracture	1	628.0	628.0		628	628
	Ecchymosis	2	57.0	57.0	0.00	57	57

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Implants Riding High	2	176.0	176.0	0.00	176	176
	Mondor's Disease	3	24.0	13.0	19.05	13	46
	Any Complication Excluding Cosmetic	121	206.4	75.0	262.66	1	1090
	II. Cosmetic Complication						
	Asymmetry	2	208.5	208.5	149.20	103	314
	Hypertrophic Scarring	11	296.5	148.0	314.20	22	1011
	Ptosis	5	179.0	103.0	144.39	60	336
	Wrinkling	2	82.0	82.0	0.00	82	82
	Any Cosmetic Complication	20	236.9	127.0	251 14	22	1011

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
12-24 Months	Total Number of Complications	43	216.3	136.0	197.22	1	736
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	14	334.6	309.0	195.18	94	736
	Baker III, IV Capsular Contracture	17	303.0	308.0	195.02	54	736
	Baker IV Capsular Contracture	3	155.3	110.0	130.07	54	302
	Breast Mass	2	29.0	29.0	35.36	4	54
	Breast Pain	4	174.8	163.0	194.65	7	366
	Hematoma	1	2.0	2.0		2	2
	Miscarriage	1	1.0	1.0		1	1
	Nipple Sensation Changes	3	378.0	351.0	46.77	351	432
	Other	1	16.0	16.0		16	16
	Soft Mass Left Costal Margin	1	16.0	16.0		16	16
	Any Complication Excluding Cosmetic	29	243.5	302.0	200.18	1	736
	II. Cosmetic Complication						
	Hypertrophic Scarring	8	166.3	128.0	161.08	1	351
	Ptosis	3	78.7	50.0	49.65	50	136
	Wrinkling	3	224.3	30.0	336.60	30	613
	Any Cosmetic Complication	14	159.9	89.0	185.16	1	613

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
24-36 Months	Total Number of Complications	14	100.9	46.5	138.19	1	421
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	4	206.8	199.0	214.49	8	421
	Baker III, IV Capsular Contracture	6	156.5	56.0	183.47	8	421
	Baker IV Capsular Contracture	2	56.0	56.0	0.00	56	56
	Breast Mass	1	135.0	135.0		135	135
	External Injury Not Related To Breast Implants	1	15.0	15.0		15	15
	Miscarriage	1	64.0	64.0		64	64
	Necrosis	2	14.0	14.0	4.24	11	17
	Nipple Sensation Changes	1	229.0	229.0		229	229
	Other	2	1.0	1.0	0.00	1	1
	Explanted Due To Right Side Being Removed	2	1.0	1.0	0.00	1	1
	Any Complication Excluding Cosmetic	14	100.9	46.5	138.19	1	421

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
AUGMENTATION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
6-12 Months	Total Number of Complications	48	197.5	161.0	182.07	1	854
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	6	349.5	255.0	323.10	23	854
	Baker III, IV Capsular Contracture	9	284.8	178.0	277.45	23	854
	Baker IV Capsular Contracture	3	155.3	143.0	96.10	66	257
	Breast Mass	2	32.5	32.5	44.55	1	64
	Breast Sensation Changes	2	79.0	79.0	0.00	79	79
	External Injury Not Related To Breast Implants	1	71.0	71.0		71	71
	Hematoma	2	14.5	14.5	2.12	13	16
	Implant Malposition/Displacement	1	23.0	23.0		23	23
	Miscarriage	2	29.5	29.5	40.31	1	58
	Nipple Sensation Changes	17	213.2	183.0	115.63	79	498
	Other	2	79.0	79.0	0.00	79	79
	Pt Requests Removal Due To Personal Reasons	2	79.0	79.0	0.00	79	79
	Any Complication Excluding Cosmetic	38	177.6	145.0	177.95	1	854
	II. Cosmetic Complication						
	Hypertrophic Scarring	10	273.1	203.0	186.85	43	544
	Any Cosmetic Complication	10	273.1	203.0	186.85	43	544

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08.48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Total Number of Complications	112	116.1	62.0	152.88	1	679
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	14	121.1	53.5	149.40	8	519
	Baker III, IV Capsular Contracture	15	118.7	68.0	144.25	8	519
	Baker IV Capsular Contracture	1	86.0	86.0		86	86
	Breast Mass	4	132.3	56.5	178.70	19	397
	Breast Pain	3	53.0	66.0	40.11	8	85
	Delayed Wound Healing	3	66.7	70.0	5.77	60	70
	External Injury Not Related To Breast Implants	1	11.0	11.0		11	11
	Extrusion	3	2.3	2.0	1.53	1	4
	Hematoma	3	99.0	91.0	77.31	26	180
	Implant Malposition/Displacement	3	99.7	92.0	102.71	1	206
	Infection	12	35.7	21.5	34.38	3	106
	Miscarriage	2	4.5	4.5	4.95	1	8
	Necrosis	1	55.0	55.0		55	55
	Nipple Sensation Changes	4	113.3	104.0	100.73	27	218
	Rash	3	19.3	18.0	2.31	18	22
	Seroma	13	55.8	43.0	35.71	12	133
	Other	21	151.9	120.0	175.15	1	639
	Capsular Contracture Secondary To Radiation Therapy	1	255.0	255.0		255	255
	Cellulitis	1	7.0	7.0		7	7
	Deep Vein Thrombosis	1	14.0	14.0		14	14

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Dog Ear Scars From Mastectomy	2	164.0	164.0	0.00	164	164
	Extra Skin	1	76.0	76.0		76	76
	Lack Of Projection	1	9.0	9.0		9	9
	Loss Of Inframammary Fold	1	120.0	120.0		120	120
	Metastatic Disease	3	149.7	1.0	257.50	1	447
	Muscle Spasm	1	108.0	108.0		108	108
	Nipple Complications	2	154.0	154.0	0.00	154	154
	Recurrent Breast Cancer	3	248.3	369.0	214.22	1	375
	Skin Lesion	1	10.0	10.0		10	10
	Stitch Abscess	1	120.0	120.0		120	120
	Tight Benilli Suture	1	1.0	1.0		1	1
	Wide Scars	1	639.0	639.0		639	639
	Any Complication Excluding Cosmetic	91	90.1	43.0	120.87	1	639
	II. Cosmetic Complication						
	Asymmetry	8	210.8	130.5	218.25	26	679
	Hypertrophic Scarring	9	254.1	178.0	229.61	35	625
	Ptosis	1	572.0	572.0		572	572
	Wrinkling	3	84.7	56.0	66.79	37	161
	Any Cosmetic Complication	21	228.5	161.0	218.24	26	679

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Total Number of Complications	76	124.6	70.0	161.68	1	679
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	6	185.3	90.0	212.28	8	519
	Baker III, IV Capsular Contracture	7	171.1	86.0	197.38	8	519
	Baker IV Capsular Contracture	1	86.0	86.0		86	86
	Breast Mass	1	83.0	83.0		83	83
	Breast Pain	1	85.0	85.0		85	85
	Delayed Wound Healing	3	66.7	70.0	5.77	60	70
	External Injury Not Related To Breast Implants	1	11.0	11.0		11	11
	Extrusion	2	2.5	2.5	2.12	1	4
	Hematoma	2	58.5	58.5	45.96	26	91
	Implant Malposition/Displacement	2	46.5	46.5	64.35	1	92
	Infection	10	36.6	21.5	37.43	3	106
	Necrosis	1	55.0	55.0		55	55
	Nipple Sensation Changes	3	78.3	27.0	88.91	27	181
	Rash	3	19.3	18.0	2.31	18	22
	Seroma	13	55.8	43.0	35.71	12	133
	Other	12	191.8	142.0	189.47	7	639
	Capsular Contracture Secondary To Radiation Therapy	1	255.0	255.0		255	255
	Cellulitis	1	7.0	7.0		7	7
	Deep Vein Thrombosis	1	14.0	14.0		14	14
	Dog Ear Scars From Mastectomy	2	164.0	164.0	0.00	164	164

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Extra Skin	1	76.0	76.0		76	76
	Loss Of Inframammary Fold	1	120.0	120.0		120	120
	Muscle Spasm	1	108.0	108.0		108	108
	Recurrent Breast Cancer	2	372.0	372.0	4 24	369	375
	Skin Lesion	1	10.0	10.0		10	10
	Wide Scars	1	639.0	639.0		639	639
	Any Complication Excluding Cosmetic	61	90.7	55.0	125.06	1	639
	II. Cosmetic Complication						
	Asymmetry	6	267.3	208.5	226.33	64	679
	Hypertrophic Scarring	7	304.7	192.0	237.20	47	625
	Wrinkling	2	99.0	99.0	87.68	37	161
	Any Cosmetic Complication	15	262.3	178.0	218.35	37	679

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08.48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
12-24 Months	Total Number of Complications	12	144.0	67.5	183.25	1	572
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	2	54.0	54.0	21.21	39	69
	Baker III, IV Capsular Contracture	2	54.0	54.0	21.21	39	69
	Breast Mass	1	19.0	19.0		19	19
	Breast Pain	1	66.0	66.0		66	66
	Hematoma	1	180.0	180.0		180	180
	Infection	1	18.0	18.0		18	18
	Other	5	153.0	154.0	180.47	1	447
	Lack Of Projection	1	9.0	9.0		9	9
	Metastatic Disease	1	447.0	447.0		447	447
	Nipple Complications	2	154.0	154.0	0.00	154	154
	Recurrent Breast Cancer	1	1.0	1.0		1	1
	Any Complication Excluding Cosmetic	11	105.1	66.0	130.22	1	447
	II. Cosmetic Complication						
	Ptosis	1	572.0	572.0		572	572
	Any Cosmetic Complication	1	572.0	572.0		572	572

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
24-36 Months	Total Number of Complications	4	37.0	13.5	56.57	1	120
	I. Complication Excluding Cosmetic						
	Other	3	40.7	1.0	68.70	1	120
	Metastatic Disease	2	1.0	1.0	0.00	1	1
	Stitch Abscess	1	120.0	120.0		120	120
	Any Complication Excluding Cosmetic	3	40.7	1.0	68.70	1	120
	II. Cosmetic Complication						
	Asymmetry	1	26.0	26.0		26	26
	Any Cosmetic Complication	1	26.0	26.0		26	26

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
RECONSTRUCTION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
6-12 Months	Total Number of Complications	20	82.8	40.0	100.73	1	397
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	6	79.2	52.0	63.40	19	168
	Baker III, IV Capsular Contracture	6	79.2	52.0	63.40	19	168
	Breast Mass	2	213.5	213.5	259.51	30	397
	Breast Pain	1	8.0	8.0		8	8
	Extrusion	1	2.0	2.0		2	2
	Implant Malposition/Displacement	1	206.0	206.0		206	206
	Infection	1	44.0	44.0		44	44
	Miscarriage	2	4.5	4.5	4.95	1	8
	Nipple Sensation Changes	1	218.0	218.0		218	218
	Other	1	1.0	1.0		1	1
	Tight Benilli Suture	1	1.0	1.0		1	1
	Any Complication Excluding Cosmetic	16	86.9	36.0	111.80	1	397
	II. Cosmetic Complication						
	Asymmetry	1	56.0	56.0		56	56
	Hypertrophic Scarring	2	77.0	77.0	59.40	35	119
	Wrinkling	1	56.0	56.0		56	56
	Any Cosmetic Complication	4	66.5	56.0	36.37	35	119

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Total Number of Complications	119	160.8	92.0	173.70	1	739
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	24	151.0	90.5	156.20	1	675
	Baker III, IV Capsular Contracture	33	158.8	95.0	172.33	1	675
	Baker IV Capsular Contracture	9	179.8	124.0	219.02	8	667
	Breast Mass	3	152.7	33.0	217.74	21	404
	Breast Pain	4	214.3	200.5	224.27	21	435
	Breast Sensation Changes	2	368.0	368.0	0.00	368	368
	Delayed Wound Healing	5	21.6	15.0	29.32	1	72
	External Injury Not Related To Breast Implants	2	31.5	31.5	13.44	22	41
	Extrusion	3	18.0	5.0	23.39	4	45
	Granuloma	2	57.5	57.5	7.78	52	63
	Hematoma	7	37.4	23.0	33.20	4	88
	Implant Malposition/Displacement	2	300.0	300.0	0.00	300	300
	Infection	2	10.5	10.5	13.44	1	20
	Inflammation	2	16.5	16.5	12.02	8	25
	Lactation Difficulties	2	30.0	30.0	0.00	30	30
	Nipple Sensation Changes	15	360.1	379.0	197.06	66	739
	Rupture	2	408.0	408.0	0.00	408	408
	Seroma	4	32.0	26.5	28.88	3	72
	Other	11	75.1	92.0	48.11	6	137
	Abnormal Mammogram	1	68.0	68.0		68	68
	Capsule Tear	1	100.0	100.0		100	100

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	False Positive For Rupture On Mammogram	1	137.0	137.0		137	137
	Muscle Spasm	2	92.0	92.0	0.00	92	92
	Siliconoma	1	137.0	137.0		137	137
	Symmastia	3	30.0	6.0	41.57	6	78
	Symmastia And Implant Malposition	2	55.0	55.0	62.23	11	99
	Any Complication Excluding Cosmetic	101	156.2	78.0	179.36	1	739
	II. Cosmetic Complication						
	Asymmetry	1	121.0	121.0		121	121
	Hypertrophic Scarring	10	201.6	176.5	180.48	1	506
	Ptosis	4	203.0	203.0	73.90	139	267
	Wrinkling	3	136.3	110.0	45.61	110	189
	Any Cosmetic Complication	18	186.6	155.0	139.10	1	506

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time. 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Total Number of Complications	65	169.0	95.0	189.21	1	739
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	11	212.1	218.0	176.37	45	675
	Baker III, IV Capsular Contracture	15	213.5	142.0	205.32	8	675
	Baker IV Capsular Contracture	4	217.3	97.0	304.98	8	667
	Breast Mass	1	21.0	21.0		21	21
	Breast Pain	2	21.0	21.0	0.00	21	21
	Breast Sensation Changes	2	368.0	368.0	0.00	368	368
	Delayed Wound Healing	5	21.6	15.0	29 32	1	72
	External Injury Not Related To Breast Implants	1	22.0	22.0		22	22
	Extrusion	2	25.0	25.0	28.28	5	45
	Granuloma	2	57.5	57.5	7.78	52	63
	Hematoma	6	41.8	31.5	34.05	4	88
	Implant Malposition/Displacement	2	300.0	300.0	0.00	300	300
	Infection	1	20.0	20.0		20	20
	Inflammation	1	25.0	25.0		25	25
	Nipple Sensation Changes	9	409.2	391.0	221.68	166	739
	Seroma	4	32.0	26.5	28.88	3	72
	Other	3	70.0	99.0	51.10	11	100
	Capsule Tear	1	100.0	100.0		100	100
	Symmastia And Implant Malposition	2	55.0	55.0	62.23	11	99
	Any Complication Excluding Cosmetic	56	164.5	81.0	198.60	1	739

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	II. Cosmetic Complication						
	Hypertrophic Scarring	4	207.8	198.0	171.43	8	427
	Ptosis	2	267.0	267.0	0.00	267	267
	Wrinkling	3	136.3	110.0	45.61	110	189
	Any Cosmetic Complication	9	197.1	198.0	119.18	8	427

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
12-24 Months	Total Number of Complications	18	126.1	67.0	142.46	1	435
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1	105.0	105.0		105	105
	Baker III, IV Capsular Contracture	3	63.7	51.0	36.68	35	105
	Baker IV Capsular Contracture	2	43.0	43.0	11.31	35	51
	Breast Pain	1	435.0	435.0		435	435
	Hematoma	1	11.0	11.0		11	11
	Infection	1	1.0	1.0		1	1
	Lactation Difficulties	2	30.0	30.0	0.00	30	30
	Nipple Sensation Changes	3	245.3	291.0	161.42	66	379
	Other	1	68.0	68.0		68	68
	Abnormal Mammogram	1	68.0	68.0		68	68
	Any Complication Excluding Cosmetic	12	125.2	58.5	152.35	1	435
	II. Cosmetic Complication						
	Asymmetry	1	121.0	121.0		121	121
	Hypertrophic Scarring	3	123.0	1.0	211.31	1	367
	Ptosis	2	139.0	139.0	0.00	139	139
	Any Cosmetic Complication	6	128.0	130.0	133.92	1	367

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
24-36 Months	Total Number of Complications	8	172.5	130.5	153.46	1	408
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	1	1.0	1.0		1	1
	Baker III, IV Capsular Contracture	3	83.0	124.0	71.01	1	124
	Baker IV Capsular Contracture	2	124.0	124.0	0.00	124	124
	External Injury Not Related To Breast Implants	1	41.0	41.0		41	41
	Rupture	2	408.0	408.0	0.00	408	408
	Other	2	137.0	137.0	0.00	137	137
	False Positive For Rupture On Mammogram	1	137.0	137.0		137	137
	Siliconoma	1	137.0	137.0		137	137
	Any Complication Excluding Cosmetic	8	172.5	130.5	153.46	1	408

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
REVISION PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
6-12 Months	Total Number of Complications	28	160.8	85.0	164.65	4	506
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	11	107.7	75.0	128.00	6	415
	Baker III, IV Capsular Contracture	12	133.3	75.0	150.87	6	415
	Baker IV Capsular Contracture	1	415.0	415.0		415	415
	Breast Mass	2	218.5	218.5	262.34	33	404
	Breast Pain	1	380.0	380.0		380	380
	Extrusion	1	4.0	4.0		4	4
	Inflammation	1	8.0	8.0		8	8
	Nipple Sensation Changes	3	327.7	403.0	130.48	177	403
	Other	5	54.8	78.0	44.91	6	92
	Muscle Spasm	2	92.0	92.0	0.00	92	92
	Symmastia	3	30.0	6.0	41.57	6	78
	Any Complication Excluding Cosmetic	25	147.4	78.0	159.20	4	415
	II. Cosmetic Complication						
	Hypertrophic Scarring	3	272.0	155.0	202.65	155	506
	Any Cosmetic Complication	3	272.0	155.0	202.65	155	506

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Total Number of Complications	477	172.0	88.0	204.21	1	1090
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	83	209.7	142.0	208.50	1	939
	Baker III, IV Capsular Contracture	101	199.6	124.0	201.96	1	939
	Baker IV Capsular Contracture	18	152.7	98.0	165.54	8	667
	Breast Mass	13	99.5	49.0	138.25	1	404
	Breast Pain	18	133.3	36.0	175.59	6	506
	Breast Sensation Changes	11	535.6	378.0	349.35	79	1090
	Delayed Wound Healing	8	38.5	39.5	32.32	1	72
	External Injury Not Related To Breast Implants	8	35.3	31.5	21.03	11	71
	Extrusion	6	10.2	4.0	17.13	1	45
	Granuloma	3	42.3	52.0	26.84	12	63
	Hematoma	25	27.3	11.0	42.19	1	180
	Implant Malposition/Displacement	6	153.7	149.0	133.98	1	300
	Infection	23	50.2	22.0	54.58	1	194
	Inflammation	4	44.8	33.5	41.87	8	104
	Lactation Difficulties	2	30.0	30.0	0.00	30	30
	Lymphadenopathy	1	8.0	8.0		8	8
	Miscarriage	7	19.3	2.0	28.66	1	64
	Necrosis	3	27.7	17.0	23.86	11	55
	Nipple Sensation Changes	70	325.5	281.5	211.38	27	777
	Placement Damage	4	1.0	1.0	0.00	1	1
	Rash	7	18.6	18.0	5.44	13	29

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Rupture	2	408.0	408.0	0.00	408	408
	Seroma	23	42.2	30.0	35.21	1	133
	Suture Reaction	4	91.3	94.0	55.32	38	139
	Other	45	119.0	79.0	152.50	1	639
	Abnormal Mammogram	1	68.0	68.0		68	68
	Capsular Contracture Secondary To Radiation Therapy	1	255.0	255.0		255	255
	Capsule Tear	1	100.0	100.0		100	100
	Cellulitis	1	7.0	7.0		7	7
	Deep Vein Thrombosis	1	14.0	14.0		14	14
	Distortion Of Breast Shape Not Related To Capsular Contracture	1	628.0	628.0		628	628
	Dog Ear Scars From Mastectomy	2	164.0	164.0	0.00	164	164
	Ecchymosis	2	57.0	57.0	0.00	57	57
	Explanted Due To Right Side Being Removed	2	1.0	1.0	0.00	1	1
	Extra Skin	1	76.0	76.0		76	76
	False Positive For Rupture On Mammogram	1	137.0	137.0		137	137
	Implants Riding High	2	176.0	176.0	0.00	176	176
	Lack Of Projection	1	9.0	9.0		9	9
	Loss Of Inframammary Fold	1	120.0	120.0		120	120
	Metastatic Disease	3	149.7	1.0	257.50	1	447
	Mondor's Disease	3	24.0	13.0	19.05	13	46
	Muscle Spasm	3	97.3	92.0	9.24	92	108
	Nipple Complications	2	154.0	154.0	0.00	154	154

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-36 Months	Pt Requests Removal Due To Personal Reasons	2	79.0	79.0	0.00	79	79
	Recurrent Breast Cancer	3	248.3	369.0	214.22	1	375
	Siliconoma	1	137.0	137.0		137	137
	Skin Lesion	1	10.0	10.0		10	10
	Soft Mass Left Costal Margin	1	16.0	16.0		16	16
	Stitch Abscess	1	120.0	120.0		120	120
	Symmastia	3	30.0	6.0	41 57	6	78
	Symmastia And Implant Malposition	2	55.0	55.0	62.23	11	99
	Tight Benilli Suture	1	1.0	1.0		1	1
	Wide Scars	1	639.0	639.0		639	639
	Any Complication Excluding Cosmetic	394	162.9	78.0	203.77	1	1090
	II. Cosmetic Complication						
	Asymmetry	11	202.2	121.0	190.51	26	679
	Hypertrophic Scarring	48	242.2	161.0	221.40	1	1011
	Ptosis	13	193.5	139.0	155.17	50	572
	Wrinkling	11	136 4	82.0	166.38	30	613
	Any Cosmetic Complication	83	215.2	148.0	201.94	1	1011

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Total Number of Complications	282	177.9	84.5	224.15	1	1090
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	38	208.6	142.5	205.96	8	939
	Baker III, IV Capsular Contracture	43	206.5	142.0	210.65	8	939
	Baker IV Capsular Contracture	5	191.0	86.0	270.56	8	667
	Breast Mass	3	51.0	49.0	31.05	21	83
	Breast Pain	10	81.2	31.0	150.69	6	506
	Breast Sensation Changes	9	637.1	681.0	298.07	357	1090
	Delayed Wound Healing	8	38.5	39.5	32.32	1	72
	External Injury Not Related To Breast Implants	5	31.0	22.0	17.92	11	50
	Extrusion	4	13.8	4.5	20.90	1	45
	Granuloma	3	42.3	52.0	26.84	12	63
	Hematoma	20	23.1	4.0	30.61	1	91
	Implant Malposition/Displacement	4	173.3	196.0	151.00	1	300
	Infection	20	54.6	30.0	56.97	3	194
	Inflammation	3	57.0	42.0	41.58	25	104
	Lymphadenopathy	1	8.0	8.0		8	8
	Miscarriage	1	2.0	2.0		2	2
	Necrosis	1	55.0	55.0		55	55
	Nipple Sensation Changes	42	377.7	358.0	242.00	27	777
	Placement Damage	4	1.0	1.0	0.00	1	1
	Rash	7	18.6	18.0	5.44	13	29
	Seroma	23	42.2	30.0	35.21	1	133

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08.48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Suture Reaction	4	91.3	94.0	55.32	38	139
	Other	23	159.9	100.0	182.59	7	639
	Capsular Contracture Secondary To Radiation Therapy	1	255.0	255.0		255	255
	Capsule Tear	1	100.0	100.0		100	100
	Cellulitis	1	7.0	7.0		7	7
	Deep Vein Thrombosis	1	14.0	14.0		14	14
	Distortion Of Breast Shape Not Related To Capsular Contracture	1	628.0	628.0		628	628
	Dog Ear Scars From Mastectomy	2	164.0	164.0	0.00	164	164
	Ecchymosis	2	57.0	57.0	0.00	57	57
	Extra Skin	1	76.0	76.0		76	76
	Implants Riding High	2	176.0	176.0	0.00	176	176
	Loss Of Inframammary Fold	1	120.0	120.0		120	120
	Mondor's Disease	3	24.0	13.0	19.05	13	46
	Muscle Spasm	1	108.0	108.0		108	108
	Recurrent Breast Cancer	2	372.0	372.0	4.24	369	375
	Skin Lesion	1	10.0	10.0		10	10
	Symmastia And Implant Malposition	2	55.0	55.0	62.23	11	99
	Wide Scars	1	639.0	639.0		639	639
	Any Complication Excluding Cosmetic	238	166.9	70.0	224.36	1	1090
	II Cosmetic Complication						

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
0-6 Months	Asymmetry	8	252.6	208.5	201.27	64	679
	Hypertrophic Scarring	22	283.0	185.0	261.95	8	1011
	Ptosis	7	204.1	267.0	125.47	60	336
	Wrinkling	7	110.1	110.0	51.22	37	189
	Any Cosmetic Complication	44	237.4	161.0	215.85	8	1011

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS
Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
12-24 Months	Total Number of Complications	73	182.2	110.0	185.30	1	736
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	17	288.1	308.0	204.50	39	736
	Baker III, IV Capsular Contracture	22	247.7	175.5	200.03	35	736
	Baker IV Capsular Contracture	5	110.4	54.0	110.80	35	302
	Breast Mass	3	25.7	19.0	25.66	4	54
	Breast Pain	6	200.0	192.5	194.63	7	435
	Hematoma	3	64.3	11.0	100.27	2	180
	Infection	2	9.5	9.5	12.02	1	18
	Lactation Difficulties	2	30.0	30.0	0.00	30	30
	Miscarriage	1	1.0	1.0		1	1
	Nipple Sensation Changes	6	311.7	351.0	128.75	66	432
	Other	7	121.3	68.0	157.71	1	447
	Abnormal Mammogram	1	68.0	68.0		68	68
	Lack Of Projection	1	9.0	9.0		9	9
	Metastatic Disease	1	447.0	447.0		447	447
	Nipple Complications	2	154.0	154.0	0.00	154	154
	Recurrent Breast Cancer	1	1.0	1.0		1	1
	Soft Mass Left Costal Margin	1	16.0	16.0		16	16
	Any Complication Excluding Cosmetic	52	186.9	107.5	185.72	1	736
	II. Cosmetic Complication						

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2. The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
12-24 Months	Asymmetry	1	121.0	121.0		121	121
	Hypertrophic Scarring	11	154.5	128.0	165.83	1	367
	Ptosis	6	181.0	137.5	196.34	50	572
	Wrinkling	3	224.3	30.0	336.60	30	613
	Any Cosmetic Complication	21	170.4	128.0	188.28	1	613

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
24-36 Months	Total Number of Complications	26	113.1	56.0	138.01	1	421
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	5	165.6	37.0	207.29	1	421
	Baker III, IV Capsular Contracture	9	132.0	56.0	153.79	1	421
	Baker IV Capsular Contracture	4	90.0	90.0	39.26	56	124
	Breast Mass	1	135.0	135.0		135	135
	External Injury Not Related To Breast Implants	2	28.0	28.0	18.38	15	41
	Miscarriage	1	64.0	64.0		64	64
	Necrosis	2	14.0	14.0	4.24	11	17
	Nipple Sensation Changes	1	229.0	229.0		229	229
	Rupture	2	408.0	408.0	0.00	408	408
	Other	7	56.9	1.0	69.90	1	137
	Explanted Due To Right Side Being Removed	2	1.0	1.0	0.00	1	1
	False Positive For Rupture On Mammogram	1	137.0	137.0		137	137
	Metastatic Disease	2	1.0	1.0	0.00	1	1
	Siliconoma	1	137.0	137.0		137	137
	Stitch Abscess	1	120.0	120.0		120	120
	Any Complication Excluding Cosmetic	25	116.6	56.0	139.69	1	421
	II. Cosmetic Complication						
	Asymmetry	1	26.0	26.0		26	26

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08.48

Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
24-36 Months	Any Cosmetic Complication	1	26.0	26.0		26	26

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08.48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days) n	Mean	Median	Std Dev	Minimum	Maximum
6-12 Months	Total Number of Complications	96	162.9	95.5	167.61	1	854
	I. Complication Excluding Cosmetic						
	Baker III Capsular Contracture	23	163.3	75.0	212.17	6	854
	Baker III, IV Capsular Contracture	27	171.8	78.0	202.91	6	854
	Baker IV Capsular Contracture	4	220.3	200.0	151.70	66	415
	Breast Mass	6	154.8	48.5	191.35	1	404
	Breast Pain	2	194.0	194.0	263.04	8	380
	Breast Sensation Changes	2	79.0	79.0	0.00	79	79
	External Injury Not Related To Breast Implants	1	71.0	71.0		71	71
	Extrusion	2	3.0	3.0	1.41	2	4
	Hematoma	2	14.5	14.5	2.12	13	16
	Implant Malposition/Displacement	2	114.5	114.5	129.40	23	206
	Infection	1	44.0	44.0		44	44
	Inflammation	1	8.0	8.0		8	8
	Miscarriage	4	17.0	4.5	27.53	1	58
	Nipple Sensation Changes	21	229.8	183.0	118.65	79	498
	Other	8	54.1	78.5	41.63	1	92
	Muscle Spasm	2	92.0	92.0	0.00	92	92
	Pt Requests Removal Due To Personal Reasons	2	79.0	79.0	0.00	79	79
	Symmastia	3	30.0	6.0	41.57	6	78
	Tight Benilli Suture	1	1.0	1.0		1	1
	Any Complication Excluding Cosmetic	79	149.7	79.0	162.52	1	854

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time. 24AUG04 08:48

Note 1. Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.

Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.6

DURATION OF POSTOPERATIVE COMPLICATIONS (EVENT LEVEL) - FDA Item 16
OVERALL PATIENTS

Time Period	Type of Complication	Duration (Days)					
		n	Mean	Median	Std Dev.	Minimum	Maximum
6-12 Months	II. Cosmetic Complication						
	Asymmetry	1	56.0	56.0		56	56
	Hypertrophic Scarring	15	246.7	161.0	182.52	35	544
	Wrinkling	1	56.0	56.0		56	56
	Any Cosmetic Complication	17	224.3	161.0	182.10	35	544

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_6.SAS Creation Date, Time: 24AUG04 08:48
Note 1: Excludes complications that occurred after explantation, planned second stage surgeries, and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast sensation changes, nipple complications, and wrinkling.
Note 2: The imputed adverse event onset dates are not used in the calculation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	113	0.2052	(0.1715,0.2389)	144	0.2618	(0.2251,0.2986)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	24	0.0436	(0.0265,0 0607)	31	0.0565	(0.0372,0.0758)
Baker III, IV Capsular Contracture	24	0.0436	(0.0265,0.0607)	32	0.0584	(0.0387, 0.078)
Baker IV Capsular Contracture	1	0.0018	(0,0.0054)	3	0.0055	(0,0.0117)
Breast Mass	1	0.0018	(0,0.0054)	3	0.0055	(0,0.0117)
Breast Pain	6	0.0109	(0.0022,0.0196)	6	0.0109	(0.0022,0.0196)
Breast Sensation Changes	8	0.0145	(0.0045,0.0245)	11	0.0200	(0.0083,0.0317)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
External Injury Not Related To Breast Implants	2	0.0036	(0,0.0087)	4	0.0073	(0.0002,0.0145)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Hematoma	12	0.0218	(0.0096, 0.034)	13	0.0236	(0.0109,0.0363)
Implant Malposition/Displacement	0	0.0000	(0, 0)	1	0.0018	(0,0.0054)
Infection	8	0.0145	(0.0045,0.0245)	8	0.0145	(0.0045,0.0245)
Inflammation	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	178	0.3263	(0.2869,0.3658)	187	0.3479	(0.3073,0.3885)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	39	0.0719	(0.0501,0.0936)	41	0.0766	(0.054,0.0992)
Baker III, IV Capsular Contracture	42	0.0774	(0.0549,0.0999)	44	0 0822	(0.0588,0.1055)
Baker IV Capsular Contracture	6	0.0111	(0.0023,0.0199)	7	0.0149	(0.0034,0.0264)
Breast Mass	11	0.0212	(0.0088,0.0336)	12	0.0237	(0.0104,0.0369)
Breast Pain	9	0.0169	(0.0059,0.0279)	9	0.0169	(0.0059,0.0279)
Breast Sensation Changes	12	0.0219	(0.0096,0.0341)	12	0.0219	(0.0096,0 0341)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
External Injury Not Related To Breast Implants	4	0.0073	(0.0002,0.0145)	6	0.0140	(0.0021,0.0259)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Hematoma	14	0.0255	(0.0123,0.0387)	14	0.0255	(0.0123,0.0387)
Implant Malposition/Displacement	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Infection	8	0.0145	(0.0045,0.0245)	8	0.0145	(0.0045,0.0245)
Inflammation	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Lactation Difficulties	0	0.0000	(0, 0)	1	0.0025	(0,0.0074)
Lymphadenopathy	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

Note: Excludes planned second stage surgeries.

Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Excessive Implant Movements	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Muscle Spasm	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Numbness In Both Hands At Night	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	1	0.0018	(0,0.0054)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Excessive Implant Movements	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	2	0.0049	(0,0.0117)
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Inframammay Fold Too High	1	0.0021	(0,0.0062)	1	0.0021	(0,0.0062)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Muscle Spasm	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Numbness In Both Hands At Night	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	1	0.0038	(0,0.0113)
Pt Requests Removal Due To Personal Reasons	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Soft Mass Left Costal Margin	1	0.0020	(0,0.0058)	1	0.0020	(0,0.0058)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Surgical Removal Of Ectopic Pregnancy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wide Scars	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	99	0.1797	(0.1477,0.2118)	123	0.2237	(0.1889,0.2586)
II. Cosmetic Complication						
Asymmetry	3	0.0054	(0,0.0116)	3	0.0054	(0,0.0116)
Hypertrophic Scarring	15	0.0273	(0.0137,0.0409)	25	0.0456	(0.0281, 0.063)
Ptosis	3	0.0054	(0,0.0116)	3	0.0054	(0,0.0116)
Wrinkling	1	0.0018	(0,0.0054)	2	0.0036	(0,0.0087)
Any Cosmetic Complication	21	0.0382	(0.0222,0.0542)	32	0.0583	(0.0387,0.0779)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Surgical Removal Of Ectopic Pregnancy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wide Scars	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	145	0.2657	(0.2285,0.3028)	154	0.2874	(0.2488,0.3261)
II. Cosmetic Complication						
Asymmetry	3	0.0054	(0,0.0116)	3	0.0054	(0,0.0116)
Hypertrophic Scarring	34	0.0627	(0.0422,0.0831)	34	0.0627	(0.0422,0.0831)
Ptosis	10	0.0191	(0.0073,0.0308)	11	0.0216	(0.0089,0.0343)
Wrinkling	4	0.0074	(0.0002,0.0146)	4	0 0074	(0.0002,0.0146)
Any Cosmetic Complication	49	0.0906	(0.0663,0.1148)	50	0.0930	(0.0684,0.1177)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	7	0.0127	(0.0034,0.0221)	13	0.0237	(0.011,0.0364)
Explant with Replacement with Study Device	4	0.0073	(0.0002,0.0144)	8	0.0146	(0.0045,0.0246)
Explant without Replacement	3	0.0054	(0,0.0116)	5	0.0091	(0.0012,0.0171)
Other Reoperations	28	0.0509	(0.0325,0.0692)	44	0.0802	(0.0575,0.1029)
Biopsy	1	0.0018	(0,0.0054)	2	0.0037	(0,0.0087)
Breast Mass Excision Dx. Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	8	0.0146	(0.0045,0.0246)	15	0.0274	(0 0137,0.0411)
Capsulorrhaphy	2	0.0036	(0,0.0087)	3	0.0055	(0,0.0116)
Capsulotomy	3	0.0055	(0,0.0116)	6	0.0110	(0.0022,0.0197)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Incision and Drainage	9	0.0163	(0.0058,0.0269)	10	0.0182	(0.007,0.0293)
Mastopexy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	20	0.0368	(0.021,0.0526)	26	0.0513	(0.0319,0.0707)
Explant with Replacement with Study Device	13	0.0239	(0.011,0.0367)	15	0.0289	(0.0144,0.0434)
Explant without Replacement	8	0.0149	(0.0047,0.0252)	12	0.0246	(0.0107,0.0385)
Other Reoperations	57	0.1046	(0.0789,0.1303)	67	0.1282	(0.0993,0.1572)
Biopsy	4	0.0074	(0.0002,0.0146)	4	0.0074	(0.0002,0.0146)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	21	0.0387	(0.0225,0.0549)	24	0.0463	(0.028,0.0645)
Capsulorrhaphy	3	0.0055	(0,0.0116)	3	0.0055	(0,0.0116)
Capsulotomy	10	0.0185	(0.0071,0.0298)	12	0.0232	(0.0101,0.0362)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	1	0.0020	(0,0.0058)	2	0.0045	(0,0.0107)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	1	0.0019	(0,0.0055)	1	0.0019	(0,0.0055)
Implant Reposition	3	0.0055	(0,0.0117)	3	0.0055	(0,0.0117)
Incision and Drainage	11	0.0201	(0.0083,0.0318)	11	0.0201	(0.0083,0.0318)
Mastopexy	1	0.0019	(0,0.0055)	2	0.0041	(0,0.0098)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following, asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	1	0.0018	(0,0.0054)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	3	0.0054	(0,0.0116)	3	0.0054	(0,0.0116)
Scar Revision	1	0.0018	(0,0.0054)	4	0.0073	(0.0002,0.0145)
Skin Adjustment	2	0.0036	(0,0.0087)	2	0.0036	(0,0.0087)
Any Reoperation	33	0.0599	(0.0401,0.0797)	53	0.0964	(0.0717, 0.121)
Total Patients Assessed	551	N/A	N/A	551	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
AUGMENTATION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	1	0.0018	(0,0.0054)	1	0.0018	(0,0.0054)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	3	0.0054	(0,0.0116)	3	0 0054	(0,0.0116)
Scar Revision	10	0.0186	(0.0072, 0.03)	12	0.0232	(0.0102,0.0362)
Skin Adjustment	3	0.0055	(0,0.0117)	5	0.0103	(0.0012,0.0194)
Any Reoperation	68	0.1241	(0.0965,0.1518)	79	0.1497	(0.1191,0.1804)
Total Patients Assessed	551	N/A	N/A	551	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following, asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	56	0.2244	(0.1727,0.2762)	74	0.2988	(0.2417,0.3559)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	8	0.0323	(0.0103,0.0543)	11	0.0449	(0.019,0.0708)
Baker III, IV Capsular Contracture	9	0.0364	(0.0131,0.0597)	13	0.0533	(0.0251,0.0814)
Baker IV Capsular Contracture	1	0.0041	(0,0.0121)	2	0.0084	(0,0.0199)
Breast Mass	1	0.0040	(0,0.0119)	4	0.0168	(0.0005,0 0331)
Breast Pain	2	0.0081	(0,0.0192)	3	0.0124	(0,0.0263)
Breast Sensation Changes	0	0.0000	(0, 0)	1	0.0041	(0,0.0121)
Delayed Wound Healing	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
External Injury Not Related To Breast Implants	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Extrusion	2	0.0080	(0,0.0191)	3	0.0122	(0,0.0258)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	2	0.0080	(0,0.0191)	2	0.0080	(0,0.0191)
Implant Malposition/Displacement	2	0.0081	(0,0.0194)	3	0.0123	(0,0.0262)
Infection	9	0.0360	(0.0129,0.0591)	10	0.0401	(0.0157,0.0644)
Inflammation	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Metastatic Disease	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	95	0.3952	(0.3324,0.4579)	102	0.4607	(0.3873,0 5341)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	15	0.0634	(0.0323,0.0946)	17	0.0795	(0.0417,0.1173)
Baker III, IV Capsular Contracture	17	0.0718	(0.0388,0.1048)	19	0.0880	(0.0487,0.1273)
Baker IV Capsular Contracture	2	0.0084	(0,0.0199)	2	0.0084	(0,0.0199)
Breast Mass	7	0.0303	(0.0082,0.0525)	8	0.0388	(0.0113,0.0664)
Breast Pain	4	0.0170	(0.0005,0.0335)	4	0.0170	(0.0005,0.0335)
Breast Sensation Changes	2	0.0088	(0,0.0209)	2	0.0088	(0,0.0209)
Delayed Wound Healing	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
External Injury Not Related To Breast Implants	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Extrusion	3	0.0122	(0,0.0258)	3	0.0122	(0,0.0258)
Granuloma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Hematoma	3	0.0152	(0,0.0329)	3	0.0152	(0,0.0329)
Implant Malposition/Displacement	4	0.0168	(0.0005,0.0331)	4	0.0168	(0.0005,0.0331)
Infection	13	0.0530	(0.0249,0.0811)	13	0.0530	(0.0249,0.0811)
Inflammation	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	1	0.0172	(0,0.0507)
Metastatic Disease	4	0.0185	(0.0005,0.0365)	4	0.0185	(0.0005,0.0365)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Miscarriage	0	0.0000	(0, 0)	2	0.0085	(0,0.0203)
Necrosis	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	1	0.0042	(0,0.0124)
Nipple Sensation Changes	2	0.0081	(0,0.0193)	4	0.0165	(0.0005,0.0325)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Recurrent Breast Cancer	1	0.0041	(0, 0.012)	2	0.0083	(0,0.0199)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	11	0.0440	(0.0186,0.0694)	11	0.0440	(0.0186,0.0694)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	11	0.0443	(0.0187,0.0699)	13	0.0526	(0.0248,0.0805)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Anaphylaxis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Back And Neck Pain Related To Large Implants	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	1	0.0041	(0, 0.012)	1	0.0041	(0, 0.012)
Capsule Tear	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Cellulitis	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Deep Vein Thrombosis	1	0 0040	(0,0.0118)	1	0.0040	(0,0.0118)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	1	0.0041	(0,0.0121)
Dog Ear Scars From Mastectomy	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Miscarriage	2	0.0085	(0,0.0203)	2	0.0085	(0,0.0203)
Necrosis	1	0.0040	(0,0.0118)	2	0.0124	(0,0.0305)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Rheumatic Disease	1	0.0042	(0,0.0124)	1	0.0042	(0,0.0124)
Nipple Sensation Changes	4	0.0165	(0.0005,0.0325)	5	0.0307	(0,0.0627)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Recurrent Breast Cancer	4	0.0172	(0.0005, 0.034)	4	0.0172	(0.0005, 0.034)
Rupture	1	0.0062	(0,0.0182)	1	0.0062	(0,0.0182)
Seroma	12	0.0486	(0.0218,0.0755)	12	0.0486	(0.0218,0.0755)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	15	0.0614	(0.0313,0.0916)	17	0.0781	(0.0407,0.1156)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Anaphylaxis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Back And Neck Pain Related To Large Implants	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	1	0.0041	(0, 0.012)	1	0.0041	(0, 0.012)
Capsule Tear	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Cellulitis	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Deep Vein Thrombosis	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0041	(0,0.0121)	1	0.0041	(0,0.0121)
Dog Ear Scars From Mastectomy	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extra Skin	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	1	0.0041	(0,0.0121)	1	0.0041	(0,0.0121)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	1	0.0041	(0, 0.012)	1	0.0041	(0, 0.012)
Nipple Complications	1	0.0041	(0, 0.012)	1	0.0041	(0, 0.012)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Numbness In Both Hands At Night	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	1	0.0040	(0,0.0119)	1	0.0040	(0,0.0119)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0 0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extra Skin	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	1	0.0046	(0,0.0135)	1	0.0046	(0,0.0135)
Loss Of Inframammary Fold	1	0.0041	(0,0.0121)	1	0.0041	(0,0.0121)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	1	0.0041	(0, 0.012)	1	0.0041	(0, 0.012)
Nipple Complications	2	0.0084	(0, 0.02)	2	0.0084	(0, 0.02)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Numbness In Both Hands At Night	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	1	0.0083	(0,0.0244)
Pain - Sternum And Under Left Arm Intermittent	1	0.0040	(0,0.0119)	1	0 0040	(0,0.0119)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Surgical Removal Of Ectopic Pregnancy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	0	0.0000	(0, 0)	1	0.0042	(0,0.0125)
Wide Scars	1	0.0040	(0,0.0119)	1	0.0040	(0,0.0119)
Any Complication Excluding Cosmetic	43	0.1722	(0.1254,0.2191)	56	0.2260	(0.1739,0.2781)
II. Cosmetic Complication						
Asymmetry	7	0.0282	(0.0076,0.0489)	10	0.0406	(0.016,0.0653)
Hypertrophic Scarring	8	0.0324	(0.0103,0.0545)	12	0.0495	(0.0222,0.0769)
Ptosis	1	0.0041	(0,0.0121)	2	0.0084	(0, 0.02)
Wrinkling	4	0.0162	(0.0005, 0.032)	5	0.0203	(0.0027, 0.038)
Any Cosmetic Complication	18	0.0729	(0.0405,0.1054)	26	0.1065	(0.0678,0.1452)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	1	0.0085	(0, 0.025)
Surgical Removal Of Ectopic Pregnancy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	1	0.0042	(0,0.0125)	1	0.0042	(0,0.0125)
Wide Scars	1	0.0040	(0,0.0119)	1	0.0040	(0,0.0119)
Any Complication Excluding Cosmetic	76	0.3145	(0.2555,0.3735)	81	0.3676	(0.2956,0.4395)
II. Cosmetic Complication						
Asymmetry	11	0.0450	(0.019, 0.071)	14	0.0714	(0.0323,0.1105)
Hypertrophic Scarring	13	0.0559	(0.026,0.0858)	14	0.0641	(0.0304,0.0977)
Ptosis	5	0.0246	(0.0027,0.0464)	9	0.0688	(0.02,0.1175)
Wrinkling	5	0.0203	(0.0027, 0.038)	6	0.0280	(0 005, 0.051)
Any Cosmetic Complication	30	0.1286	(0.085,0.1723)	35	0.1754	(0.117,0.2338)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	7	0.0280	(0.0076,0.0485)	20	0.0805	(0.0466,0.1143)
Explant with Replacement with Study Device	4	0.0162	(0.0005, 0.032)	13	0.0531	(0.025,0.0812)
Explant without Replacement	3	0.0120	(0,0.0255)	7	0.0284	(0.0077,0.0492)
Other Reoperations	21	0.0848	(0.0501,0.1194)	40	0.1632	(0.1169,0.2094)
Biopsy	4	0.0162	(0.0005,0.0319)	6	0.0248	(0.0052,0.0444)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	3	0.0122	(0, 0.026)	6	0.0251	(0.0053,0.0449)
Capsulorrhaphy	2	0.0081	(0,0.0193)	2	0.0081	(0,0.0193)
Capsulotomy	5	0.0203	(0.0027,0.0379)	12	0.0495	(0.0222,0.0767)
Create Inframmary Fold	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	3	0.0127	(0,0.0269)
Implant Reposition	4	0.0162	(0.0005, 0.032)	10	0.0412	(0.0162,0.0663)
Incision and Drainage	3	0.0120	(0,0.0256)	3	0.0120	(0,0.0256)
Mastopexy	1	0.0041	(0, 0.012)	1	0.0041	(0, 0.012)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

· Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	29	0.1180	(0.0776,0.1583)	31	0.1330	(0.0883,0.1778)
Explant with Replacement with Study Device	18	0.0744	(0.0413,0.1075)	18	0.0744	(0.0413,0.1075)
Explant without Replacement	11	0.0462	(0.0195,0.0729)	13	0.0622	(0.0279,0.0965)
Other Reoperations	52	0.2144	(0.1626,0.2661)	53	0.2222	(0.1688,0.2757)
Biopsy	8	0.0339	(0.0108, 0.057)	8	0.0339	(0.0108, 0.057)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	1	0.0083	(0,0.0244)
Capsulectomy	9	0.0383	(0.0137,0.0629)	9	0.0383	(0.0137,0.0629)
Capsulorrhaphy	2	0.0081	(0,0.0193)	2	0.0081	(0,0.0193)
Capsulotomy	13	0.0539	(0.0254,0.0824)	13	0.0539	(0.0254,0.0824)
Create Inframmary Fold	1	0.0040	(0,0.0118)	1	0.0040	(0,0.0118)
Excise Breast Mass	0	0.0000	(0, 0)	0	0 0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	1	0.0043	(0,0.0129)	1	0.0043	(0,0.0129)
Implant Pocket Revision	4	0.0171	(0.0005,0.0337)	4	0.0171	(0.0005,0.0337)
Implant Reposition	12	0.0501	(0.0225,0.0778)	12	0.0501	(0.0225,0.0778)
Incision and Drainage	3	0.0120	(0,0.0256)	4	0.0205	(0,0.0417)
Mastopexy	2	0.0085	(0,0.0203)	2	0.0085	(0,0.0203)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	1	0.0041	(0, 0.012)	2	0.0083	(0,0.0198)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	1	0 0040	(0, 0.012)	1	0.0040	(0, 0.012)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	0	0.0000	(0, 0)	1	0.0042	(0,0.0125)
Scar Revision	1	0.0041	(0,0.0121)	3	0.0123	(0,0.0262)
Skin Adjustment	4	0.0162	(0.0005, 0.032)	9	0.0370	(0.0133,0.0608)
Any Reoperation	25	0.1000	(0.0628,0.1372)	48	0.1930	(0.144,0.2421)
Total Patients Assessed	251	N/A	N/A	251	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
RECONSTRUCTION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	2	0.0083	(0,0.0198)	2	0.0083	(0,0.0198)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	1	0.0040	(0, 0.012)	1	0.0040	(0, 0.012)
Revision Of Breast / External To Pocket	1	0.0045	(0,0.0133)	1	0.0045	(0,0.0133)
Revision Of Wound Closure	1	0.0042	(0,0.0125)	1	0.0042	(0,0.0125)
Scar Revision	5	0.0215	(0.0028,0.0401)	5	0.0215	(0.0028,0.0401)
Skin Adjustment	10	0.0414	(0.0163,0.0665)	10	0.0414	(0.0163,0.0665)
Any Reoperation	63	0 2554	(0.2009,0.3099)	64	0.2630	(0.2071, 0.319)
Total Patients Assessed	251	N/A	N/A	251	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	51	0.2508	(0.1912,0.3104)	67	0.3302	(0.2654,0.3949)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	16	0.0788	(0.0417,0.1158)	26	0.1286	(0.0824,0.1747)
Baker III, IV Capsular Contracture	18	0.0885	(0.0495,0.1276)	27	0.1333	(0.0865,0.1802)
Baker IV Capsular Contracture	5	0.0246	(0.0033,0.0458)	6	0.0296	(0.0063, 0.053)
Breast Mass	4	0.0196	(0.0006,0.0387)	6	0.0296	(0.0063,0.0529)
Breast Pain	1	0.0049	(0,0.0145)	2	0.0099	(0,0.0236)
Breast Sensation Changes	2	0.0098	(0,0.0233)	2	0.0098	(0,0.0233)
Delayed Wound Healing	4	0.0196	(0.0006,0.0386)	4	0.0196	(0.0006,0.0386)
External Injury Not Related To Breast Implants	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Extrusion	2	0.0098	(0,0.0233)	3	0.0148	(0,0.0313)
Granuloma	2	0.0099	(0,0.0234)	2	0.0099	(0,0.0234)
Hematoma	5	0.0245	(0.0033,0.0456)	5	0.0245	(0.0033,0.0456)
Implant Malposition/Displacement	3	0.0148	(0,0.0313)	4	0.0197	(0.0006,0.0388)
Infection	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Inflammation	1	0.0050	(0,0.0146)	3	0.0149	(0,0.0317)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	83	0.4129	(0.3446,0.4813)	87	0.4362	(0.3669,0.5055)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	32	0.1601	(0.1092,0.2111)	32	0.1601	(0.1092,0.2111)
Baker III, IV Capsular Contracture	33	0.1650	(0.1134,0.2165)	34	0.1716	(0.1189,0.2243)
Baker IV Capsular Contracture	8	0.0399	(0.0128, 0.067)	10	0.0542	(0.021,0.0874)
Breast Mass	9	0.0456	(0.0164,0.0748)	11	0.0580	(0.0245,0.0914)
Breast Pain	4	0.0203	(0.0006,0.0399)	4	0.0203	(0.0006,0.0399)
Breast Sensation Changes	3	0 0150	(0, 0.032)	4	0.0213	(0.0005,0.0421)
Delayed Wound Healing	4	0.0196	(0.0006,0.0386)	4	0.0196	(0.0006,0.0386)
External Injury Not Related To Breast Implants	1	0.0049	(0,0.0145)	2	0.0123	(0,0.0295)
Extrusion	3	0.0148	(0,0.0313)	3	0.0148	(0,0.0313)
Granuloma	2	0.0099	(0,0.0234)	2	0.0099	(0,0.0234)
Hematoma	6	0.0297	(0.0063,0.0532)	6	0.0297	(0.0063,0.0532)
Implant Malposition/Displacement	5	0.0252	(0.0034, 0.047)	5	0.0252	(0.0034, 0.047)
Infection	2	0.0102	(0,0.0243)	2	0.0102	(0,0.0243)
Inflammation	3	0.0149	(0,0.0317)	3	0.0149	(0,0.0317)
Lactation Difficulties	1	0.0053	(0,0.0158)	1	0.0053	(0,0.0158)
Lymphadenopathy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Miscarriage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	1	0.0050	(0,0.0147)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	2	0.0100	(0,0.0237)
Nipple Sensation Changes	9	0.0442	(0.016,0.0724)	12	0.0591	(0.0267,0.0915)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Recurrent Breast Cancer	0	0.0000	(0, 0)	1	0.0050	(0,0.0147)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	4	0.0196	(0.0006,0.0386)	4	0.0196	(0.0006,0.0386)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	2	0.0098	(0,0.0233)	6	0.0296	(0.0063,0.0529)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Anaphylaxis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Back And Neck Pain Related To Large Implants	0	0.0000	(0, 0)	1	0.0050	(0,0.0147)
Capsular Contracture Secondary To Radiation Therapy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsule Tear	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Cellulitis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Deep Vein Thrombosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Dog Ear Scars From Mastectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Miscarriage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	1	0.0050	(0,0.0147)	1	0.0050	(0,0.0147)
New Diagnosis of Rheumatic Disease	2	0.0100	(0,0.0237)	2	0.0100	(0,0.0237)
Nipple Sensation Changes	16	0.0799	(0.0423,0.1175)	17	0.0862	(0.0469,0.1255)
Placement Damage	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rash	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Recurrent Breast Cancer	1	0.0050	(0,0.0147)	1	0.0050	(0,0.0147)
Rupture	3	0.0176	(0,0.0374)	4	0.0248	(0.0007,0.0489)
Seroma	4	0.0196	(0.0006,0.0386)	4	0.0196	(0.0006,0.0386)
Suture Reaction	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Other	11	0.0566	(0.024,0.0892)	12	0.0636	(0.0285,0.0987)
Abnormal Mammogram	1	0.0054	(0, 0.016)	1	0.0054	(0, 0.016)
Anaphylaxis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Back And Neck Pain Related To Large Implants	1	0.0050	(0,0.0147)	1	0.0050	(0,0.0147)
Capsular Contracture Secondary To Radiation Therapy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsule Tear	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Cellulitis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Deep Vein Thrombosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Dog Ear Scars From Mastectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	0	0.0000	(0, 0)	1	0.0050	(0,0.0147)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Numbness In Both Hands At Night	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excessive Implant Movements	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	1	0.0072	(0,0.0212)
Implants Riding High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Muscle Spasm	1	0.0050	(0,0.0147)	1	0.0050	(0,0.0147)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	1	0.0061	(0,0.0179)	1	0.0061	(0,0.0179)
Numbness In Both Hands At Night	1	0.0053	(0,0.0156)	1	0.0053	(0,0.0156)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Siliconoma	0	0.0000	(0, 0)	1	0.0072	(0,0.0212)
Skin Lesion	1	0.0053	(0,0.0156)	1	0.0053	(0,0.0156)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Surgical Removal Of Ectopic Pregnancy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	2	0.0099	(0,0.0236)
Symmastia And Implant Malposition	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wide Scars	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	44	0.2162	(0.1596,0.2727)	62	0.3055	(0.2421,0.3689)
II. Cosmetic Complication						
Asymmetry	1	0.0050	(0,0.0146)	3	0.0149	(0,0.0316)
Hypertrophic Scarring	6	0.0296	(0.0063,0.0529)	8	0.0395	(0.0127,0.0664)
Ptosis	1	0.0050	(0,0.0146)	2	0.0099	(0,0.0236)
Wrinkling	3	0.0148	(0,0.0314)	3	0.0148	(0,0.0314)
Any Cosmetic Complication	11	0.0543	(0.0231,0.0855)	15	0.0742	(0.0381,0.1103)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Surgical Removal Of Ectopic Pregnancy	1	0.0053	(0,0.0156)	1	0.0053	(0,0.0156)
Symmastia	2	0.0099	(0,0.0236)	2	0.0099	(0,0.0236)
Symmastia And Implant Malposition	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Wide Scars	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Any Complication Excluding Cosmetic	73	0.3628	(0.2962,0.4295)	77	0.3862	(0.3182,0.4542)
II. Cosmetic Complication						
Asymmetry	4	0.0200	(0.0006,0.0395)	5	0.0270	(0.0034,0.0507)
Hypertrophic Scarring	12	0.0603	(0.0272,0.0934)	12	0.0603	(0.0272,0.0934)
Ptosis	4	0.0215	(0.0006,0.0425)	4	0.0215	(0.0006,0.0425)
Wrinkling	4	0.0201	(0.0006,0.0396)	4	0 0201	(0.0006,0.0396)
Any Cosmetic Complication	23	0.1169	(0.0719,0.1619)	23	0.1169	(0.0719,0.1619)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	5	0.0245	(0.0033,0.0456)	12	0.0589	(0.0266,0.0912)
Explant with Replacement with Study Device	3	0.0147	(0,0.0313)	8	0.0395	(0.0127,0.0663)
Explant without Replacement	2	0.0098	(0,0.0234)	4	0.0197	(0.0006,0.0388)
Other Reoperations	16	0.0787	(0.0417,0.1157)	27	0.1332	(0.0864, 0.18)
Biopsy	3	0.0148	(0,0.0314)	5	0.0247	(0.0033,0.0461)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	3	0.0148	(0,0.0313)	9	0.0447	(0.0161,0.0732)
Capsulorrhaphy	1	0.0049	(0,0.0145)	1	0.0049	(0,0.0145)
Capsulotomy	2	0.0099	(0,0.0236)	8	0.0397	(0.0127,0.0666)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	1	0.0050	(0,0.0146)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0 0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	0	0.0000	(0, 0)	2	0.0099	(0,0.0236)
Incision and Drainage	5	0.0245	(0.0033,0.0457)	5	0.0245	(0.0033,0.0457)
Mastopexy	0	0.0000	(0, 0)	2	0.0099	(0,0.0236)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	20	0.1003	(0.0585,0.1421)	25	0.1327	(0.0837,0.1817)
Explant with Replacement with Study Device	12	0.0609	(0.0274,0.0944)	14	0.0753	(0.0369,0.1138)
Explant without Replacement	8	0.0405	(0.013,0.0679)	11	0.0595	(0 0251,0.0938)
Other Reoperations	34	0.1691	(0.1172,0.2209)	41	0.2146	(0.1556,0.2736)
Biopsy	6	0.0300	(0.0063,0.0537)	7	0.0372	(0.0098,0.0645)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	10	0.0499	(0.0197, 0.08)	12	0.0636	(0.0284,0.0987)
Capsulorrhaphy	2	0.0100	(0,0.0239)	2	0.0100	(0,0.0239)
Capsulotomy	10	0.0500	(0.0198,0.0802)	11	0.0571	(0.0241,0.0902)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	1	0.0050	(0,0.0146)	1	0.0050	(0,0.0146)
Exploration Right Breast With Evacuation Of Hematoma	1	0.0053	(0,0.0156)	1	0.0053	(0,0.0156)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	4	0.0203	(0.0006,0.0401)	5	0.0274	(0.0034,0.0515)
Incision and Drainage	5	0.0245	(0.0033,0.0457)	5	0.0245	(0.0033,0.0457)
Mastopexy	2	0.0099	(0,0.0236)	3	0.0172	(0,0.0367)
Needle Aspiration	0	0.0000	(0, 0)	1	0.0065	(0,0.0193)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	2	0.0098	(0,0.0233)	2	0.0098	(0,0.0233)
Scar Revision	1	0.0049	(0,0.0145)	3	0.0150	(0,0.0319)
Skin Adjustment	2	0.0098	(0,0.0233)	5	0.0247	(0.0033,0.0461)
Any Reoperation	21	0.1026	(0.0611,0.1442)	32	0.1566	(0.1068,0.2064)
Total Patients Assessed	205	N/A	N/A	205	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
REVISION PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	1	0.0072	(0,0.0214)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	1	0.0063	(0,0.0187)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	2	0.0098	(0,0.0233)	2	0.0098	(0,0.0233)
Scar Revision	5	0.0254	(0.0034,0.0474)	6	0.0322	(0.0067,0.0577)
Skin Adjustment	7	0.0350	(0.0095,0.0605)	7	0.0350	(0.0095,0.0605)
Any Reoperation	43	0.2125	(0.1561, 0.269)	51	0.2629	(0.2002,0.3257)
Total Patients Assessed	205	N/A	N/A	205	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	220	0.2191	(0.1935,0.2447)	285	0.2847	(0.2567,0.3127)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	48	0.0480	(0.0347,0.0612)	68	0.0683	(0.0527, 0.084)
Baker III, IV Capsular Contracture	51	0.0509	(0.0373,0.0646)	72	0.0724	(0.0563,0.0885)
Baker IV Capsular Contracture	7	0.0070	(0.0018,0.0121)	11	0.0111	(0.0046,0.0176)
Breast Mass	6	0.0060	(0.0012,0.0107)	13	0.0131	(0.006,0.0202)
Breast Pain	9	0.0090	(0.0031,0.0148)	11	0.0110	(0.0045,0.0175)
Breast Sensation Changes	10	0.0099	(0.0038,0.0161)	14	0.0140	(0.0067,0.0213)
Delayed Wound Healing	5	0.0050	(0.0006,0.0093)	5	0.0050	(0.0006,0.0093)
External Injury Not Related To Breast Implants	4	0.0040	(0.0001,0.0079)	6	0 0060	(0.0012,0.0108)
Extrusion	4	0.0040	(0.0001,0.0079)	6	0.0060	(0.0012,0.0108)
Granuloma	3	0.0030	(0,0.0064)	3	0.0030	(0,0.0064)
Hematoma	19	0.0189	(0.0105,0.0273)	20	0.0199	(0.0113,0.0285)
Implant Malposition/Displacement	5	0.0050	(0.0006,0.0094)	8	0.0080	(0.0025,0.0136)
Infection	18	0.0179	(0.0097,0.0261)	19	0.0189	(0.0105,0.0273)
Inflammation	3	0.0030	(0,0.0064)	5	0.0050	(0.0006,0.0094)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Metastatic Disease	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8 7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	356	0.3604	(0.3304,0.3905)	376	0.3890	(0.3577,0.4202)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	86	0.0878	(0.0701,0.1056)	90	0 0935	(0.075, 0.112)
Baker III, IV Capsular Contracture	92	0.0939	(0.0756,0.1122)	97	0.1011	(0.0819,0.1203)
Baker IV Capsular Contracture	16	0.0163	(0.0084,0.0243)	19	0.0220	(0.0117,0.0324)
Breast Mass	27	0.0287	(0.018,0.0395)	31	0.0345	(0.0224,0.0465)
Breast Pain	17	0.0178	(0.0094,0.0262)	17	0.0178	(0.0094,0.0262)
Breast Sensation Changes	17	0.0172	(0.0091,0.0252)	18	0.0185	(0.01, 0.027)
Delayed Wound Healing	5	0.0050	(0.0006,0.0093)	5	0.0050	(0.0006,0.0093)
External Injury Not Related To Breast Implants	6	0.0060	(0.0012,0.0108)	9	0.0121	(0.0034,0.0209)
Extrusion	6	0.0060	(0.0012,0.0108)	6	0.0060	(0.0012,0.0108)
Granuloma	3	0.0030	(0,0.0064)	3	0.0030	(0,0.0064)
Hematoma	23	0.0233	(0.0139,0.0327)	23	0.0233	(0.0139,0.0327)
Implant Malposition/Displacement	10	0.0103	(0.0039,0.0166)	10	0.0103	(0.0039,0 0166)
Infection	23	0.0231	(0.0138,0.0324)	23	0.0231	(0.0138,0.0324)
Inflammation	5	0.0050	(0.0006,0.0094)	5	0.0050	(0.0006,0.0094)
Lactation Difficulties	1	0.0011	(0,0.0032)	2	0 0026	(0,0.0062)
Lymphadenopathy	1	0.0010	(0,0.0029)	2	0.0031	(0,0 0077)
Metastatic Disease	4	0.0043	(0.0001,0.0084)	4	0.0043	(0.0001,0.0084)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Miscarriage	2	0.0020	(0,0.0048)	7	0.0071	(0.0019,0.0123)
Necrosis	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	1	0.0010	(0, 0.003)
New Diagnosis of Rheumatic Disease	0	0.0000	(0, 0)	3	0.0031	(0,0.0065)
Nipple Sensation Changes	42	0.0418	(0.0295,0.0542)	61	0.0611	(0.0462,0.0759)
Placement Damage	4	0.0040	(0.0001,0.0079)	4	0.0040	(0.0001,0.0079)
Rash	4	0.0040	(0.0001,0.0079)	4	0.0040	(0.0001,0.0079)
Recurrent Breast Cancer	1	0.0010	(0, 0.003)	3	0.0030	(0,0.0065)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	19	0.0189	(0.0105,0.0273)	19	0.0189	(0.0105,0.0273)
Suture Reaction	3	0.0030	(0,0.0064)	3	0.0030	(0,0.0064)
Other	20	0.0199	(0.0113,0.0286)	27	0.0270	(0.017,0.0371)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Anaphylaxis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Back And Neck Pain Related To Large Implants	0	0.0000	(0, 0)	1	0.0010	(0, 0.003)
Capsular Contracture Secondary To Radiation Therapy	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Capsule Tear	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Cellulitis	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Deep Vein Thrombosis	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0010	(0, 0.003)	2	0.0020	(0,0.0048)
Dog Ear Scars From Mastectomy	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Miscarriage	8	0.0082	(0.0025,0.0138)	9	0.0100	(0.0033,0.0167)
Necrosis	1	0.0010	(0,0.0029)	3	0.0039	(0,0.0084)
New Diagnosis of Breast Cancer	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
New Diagnosis of Rheumatic Disease	6	0.0063	(0.0013,0.0112)	6	0.0063	(0.0013,0.0112)
Nipple Sensation Changes	71	0.0716	(0.0555,0.0876)	79	0.0838	(0.0658,0.1018)
Placement Damage	4	0.0040	(0.0001,0.0079)	4	0.0040	(0.0001,0.0079)
Rash	5	0.0050	(0.0006,0.0094)	5	0.0050	(0.0006,0.0094)
Recurrent Breast Cancer	5	0.0052	(0.0006,0.0097)	5	0.0052	(0.0006,0 0097)
Rupture	4	0.0049	(0.0001,0.0097)	6	0.0077	(0.0015,0.0139)
Seroma	21	0.0210	(0.0121,0.0299)	21	0.0210	(0.0121,0.0299)
Suture Reaction	3	0.0030	(0,0.0064)	3	0.0030	(0,0.0064)
Other	37	0.0381	(0.026,0.0502)	44	0.0497	(0.0349,0.0646)
Abnormal Mammogram	1	0.0011	(0,0.0032)	1	0.0011	(0,0.0032)
Anaphylaxis	1	0.0011	(0,0.0031)	1	0.0011	(0,0.0031)
Back And Neck Pain Related To Large Implants	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Capsular Contracture Secondary To Radiation Therapy	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Capsule Tear	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Cellulitis	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Deep Vein Thrombosis	1	0.0010	(0,0.0029)	2	0.0025	(0,0.0061)
Distortion Of Breast Shape Not Related To Capsular Contracture	2	0.0020	(0,0.0048)	2	0.0020	(0,0.0048)
Dog Ear Scars From Mastectomy	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	2	0.0020	(0,0.0047)	2	0.0020	(0,0.0047)
Excessive Implant Movements	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Extra Skin	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Inframammay Fold Too High	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Mondor's Disease	2	0.0020	(0,0.0047)	2	0.0020	(0,0.0047)
Muscle Spasm	1	0.0010	(0, 0.003)	2	0 0020	(0,0.0048)
Nipple Complications	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Numbness In Both Hands At Night	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pt Requests Removal Due To Personal Reasons	0	0.0000	(0, 0)	1	0.0010	(0, 0.003)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Soft Mass Left Costal Margin	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Ecchymosis	2	0.0020	(0,0.0047)	2	0.0020	(0,0.0047)
Excessive Implant Movements	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	2	0.0030	(0,0.0071)
Extra Skin	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	1	0.0015	(0,0.0045)
Implants Riding High	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Inframammay Fold Too High	1	0.0013	(0,0.0038)	1	0.0013	(0,0.0038)
Lack Of Projection	1	0.0011	(0,0.0032)	1	0.0011	(0,0.0032)
Loss Of Inframammary Fold	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Mondor's Disease	2	0.0020	(0,0.0047)	2	0.0020	(0,0.0047)
Muscle Spasm	2	0.0020	(0,0.0048)	2	0.0020	(0,0.0048)
Nipple Complications	2	0.0020	(0,0.0049)	2	0.0020	(0,0.0049)
Nipple Related Unplanned	1	0.0013	(0,0.0037)	1	0.0013	(0,0.0037)
Numbness In Both Hands At Night	1	0.0011	(0,0.0032)	1	0.0011	(0,0.0032)
Occasional Burning Discomfort Of Skin.	0	0.0000	(0, 0)	1	0.0015	(0,0.0044)
Pain - Sternum And Under Left Arm Intermittent	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Positive Antinuclear Antibodies Negative For Lupus	0	0.0000	(0, 0)	1	0.0027	(0, 0.008)
Pt Requests Removal Due To Personal Reasons	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Siliconoma	0	0.0000	(0, 0)	1	0.0015	(0,0.0045)
Skin Lesion	2	0.0021	(0,0.0049)	2	0.0021	(0,0.0049)
Soft Mass Left Costal Margin	1	0.0012	(0,0.0035)	1	0.0012	(0,0.0035)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Surgical Removal Of Ectopic Pregnancy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia	0	0.0000	(0, 0)	2	0.0020	(0,0.0048)
Symmastia And Implant Malposition	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Tight Benilli Suture	0	0.0000	(0, 0)	1	0.0010	(0, 0.003)
Wide Scars	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Any Complication Excluding Cosmetic	186	0.1852	(0.1612,0.2092)	241	0.2408	(0.2143,0.2673)
II. Cosmetic Complication						
Asymmetry	11	0.0110	(0.0045,0.0174)	16	0.0160	(0.0082,0.0238)
Hypertrophic Scarring	29	0.0290	(0.0186,0.0394)	45	0.0452	(0.0323,0.0582)
Ptosis	5	0.0050	(0.0006,0.0094)	7	0.0070	(0.0018,0.0122)
Wrinkling	8	0.0080	(0.0025,0.0135)	10	0.0100	(0.0038,0.0162)
Any Cosmetic Complication	50	0.0500	(0.0365,0.0635)	73	0.0733	(0.0571,0.0895)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Stitch Abscess	0	0.0000	(0, 0)	1	0.0015	(0,0.0046)
Surgical Removal Of Ectopic Pregnancy	1	0.0011	(0,0.0031)	1	0.0011	(0,0.0031)
Symmastia	2	0.0020	(0,0.0048)	2	0.0020	(0,0.0048)
Symmastia And Implant Malposition	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Tight Benilli Suture	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Wide Scars	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Any Complication Excluding Cosmetic	294	0.2973	(0.2687,0.3259)	312	0.3238	(0.2938,0.3539)
II. Cosmetic Complication						
Asymmetry	18	0.0181	(0.0098,0.0264)	22	0.0242	(0.014,0.0343)
Hypertrophic Scarring	59	0.0605	(0.0455,0.0754)	60	0.0619	(0.0467,0.0771)
Ptosis	19	0.0208	(0.0115,0.0301)	24	0.0289	(0.0172,0.0406)
Wrinkling	13	0.0132	(0.0061,0.0203)	14	0.0145	(0.0069,0.0221)
Any Cosmetic Complication	102	0.1050	(0.0856,0.1243)	108	0.1140	(0.0935,0.1345)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	19	0.0189	(0.0105,0.0273)	45	0.0449	(0.0321,0.0577)
Explant with Replacement with Study Device	11	0.0110	(0.0045,0.0174)	29	0.0291	(0.0187,0.0395)
Explant without Replacement	8	0.0080	(0.0025,0.0135)	16	0.0160	(0.0082,0.0239)
Other Reoperations	65	0.0649	(0.0496,0.0801)	111	0.1114	(0.0918,0.1309)
Biopsy	8	0.0080	(0.0025,0.0135)	13	0.0131	(0.006,0.0202)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	14	0.0140	(0.0067,0.0213)	30	0.0304	(0.0197, 0.041)
Capsulorrhaphy	5	0.0050	(0.0006,0.0094)	6	0.0060	(0.0012,0.0108)
Capsulotomy	10	0.0100	(0.0038,0.0162)	26	0.0262	(0.0163,0.0362)
Create Inframmary Fold	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	1	0.0010	(0, 0.003)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	3	0.0031	(0,0.0065)
Implant Reposition	6	0.0060	(0.0012,0.0108)	14	0.0141	(0.0068,0.0215)
Incision and Drainage	17	0.0169	(0.0089,0.0249)	18	0.0179	(0.0097,0.0261)
Mastopexy	1	0.0010	(0, 0.003)	3	0.0030	(0,0.0065)
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	69	0.0699	(0.054,0.0858)	82	0.0883	(0.0698,0.1068)
Explant with Replacement with Study Device	43	0.0438	(0.031,0.0566)	47	0.0499	(0.0359, 0.064)
Explant without Replacement	27	0.0278	(0.0174,0.0381)	36	0.0406	(0.0274,0.0538)
Other Reoperations	143	0.1446	(0.1227,0.1666)	161	0.1700	(0.1458,0.1943)
Biopsy	18	0.0184	(0.01,0.0268)	19	0.0199	(0.011,0.0288)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	1	0.0015	(0,0.0044)
Capsulectomy	40	0.0409	(0.0285,0.0533)	45	0.0485	(0.0345,0.0625)
Capsulorrhaphy	7	0.0070	(0.0018,0.0122)	7	0.0070	(0.0018,0.0122)
Capsulotomy	33	0.0336	(0.0223,0.0448)	36	0.0379	(0.0257,0.0501)
Create Inframmary Fold	1	0.0010	(0,0.0029)	1	0.0010	(0,0.0029)
Excise Breast Mass	1	0.0012	(0,0.0035)	2	0.0027	(0,0.0065)
Excision Of Skin Lesion	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Exploration Right Breast With Evacuation Of Hematoma	1	0.0011	(0,0.0031)	1	0.0011	(0,0.0031)
Flap Coverage Of Expander	1	0.0010	(0,0.0031)	1	0.0010	(0,0.0031)
Implant Pocket Revision	5	0.0052	(0.0006,0.0097)	5	0.0052	(0.0006,0.0097)
Implant Reposition	19	0.0194	(0.0107, 0.028)	20	0.0209	(0.0118, 0.03)
Incision and Drainage	19	0.0190	(0.0105,0.0274)	20	0.0205	(0.0116,0.0295)
Mastopexy	5	0.0051	(0.0006,0.0096)	7	0.0080	(0.002, 0.014)
Needle Aspiration	0	0.0000	(0, 0)	1	0.0014	(0,0.0042)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2. Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	1	0.0010	(0, 0.003)	3	0.0030	(0,0.0065)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	5	0.0050	(0.0006,0.0093)	6	0.0060	(0.0012,0.0108)
Scar Revision	3	0.0030	(0,0.0064)	10	0.0101	(0.0039,0.0164)
Skin Adjustment	8	0.0080	(0.0025,0.0135)	16	0.0161	(0.0083,0.0239)
Any Reoperation	79	0.0786	(0.0619,0.0952)	133	0.1326	(0.1116,0.1536)
Total Patients Assessed	1007	N/A	N/A	1007	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.1

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (PATIENT LEVEL)
OVERALL PATIENTS

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Nipple Related Procedure (unplanned)	3	0.0030	(0,0.0065)	4	0.0046	(0,0.0091)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	1	0.0014	(0,0.0041)
Removal Of Nodule On Chest Wall	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Revision Of Breast / External To Pocket	1	0.0011	(0,0.0031)	1	0.0011	(0,0.0031)
Revision Of Wound Closure	6	0.0060	(0.0012,0.0108)	6	0.0060	(0.0012,0.0108)
Scar Revision	20	0.0207	(0.0117,0.0296)	23	0.0249	(0.0148, 0.035)
Skin Adjustment	20	0.0203	(0.0115,0.0291)	22	0.0232	(0.0135,0.0329)
Any Reoperation	174	0.1746	(0.151,0.1981)	194	0.2021	(0.1764,0.2278)
Total Patients Assessed	1007	N/A	N/A	1007	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	152	0.1350	(0.115,0.1549)	199	0.1770	(0.1547,0.1993)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	29	0.0258	(0.0165, 0.035)	39	0.0348	(0.024,0.0455)
Baker III, IV Capsular Contracture	30	0.0266	(0.0172,0.0361)	42	0.0375	(0.0263,0.0486)
Baker IV Capsular Contracture	1	0.0009	(0,0.0026)	4	0.0036	(0.0001,0.0071)
Breast Mass	2	0.0018	(0,0.0042)	4	0.0036	(0.0001,0.0071)
Breast Pain	10	0.0089	(0.0034,0.0144)	10	0.0089	(0.0034,0.0144)
Breast Sensation Changes	11	0.0098	(0.004,0.0155)	16	0.0142	(0.0073,0.0212)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
External Injury Not Related To Breast Implants	3	0.0027	(0,0.0057)	5	0.0045	(0.0006,0.0084)
Extrusion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Granuloma	1	0.0009	(0,0.0026)	1	0.0009	(0,0.0026)
Hematoma	12	0.0106	(0.0047,0.0166)	13	0.0115	(0.0053,0.0178)
Implant Malposition/Displacement	0	0.0000	(0, 0)	1	0.0009	(0,0.0027)
Infection	8	0.0071	(0.0022, 0.012)	8	0.0071	(0.0022, 0.012)
Inflammation	2	0.0018	(0,0.0042)	2	0.0018	(0,0.0042)
Lactation Difficulties	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Lymphadenopathy	1	0.0009	(0,0.0026)	1	0.0009	(0,0.0026)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication	252	0.2265	(0.2018,0.2511)	267	0.2440	(0.2184,0.2697)
I. Complication Excluding Cosmetic						
Baker III Capsular Contracture	52	0.0470	(0.0345,0.0594)	56	0.0515	(0.0383,0.0647)
Baker III, IV Capsular Contracture	57	0.0515	(0.0384,0.0645)	61	0.0560	(0.0423,0.0697)
Baker IV Capsular Contracture	7	0.0063	(0.0017, 0.011)	9	0.0101	(0.0031,0.0171)
Breast Mass	12	0.0113	(0.0049,0.0176)	13	0.0125	(0.0057,0.0192)
Breast Pain	14	0.0129	(0.0062,0.0196)	14	0.0129	(0.0062,0.0196)
Breast Sensation Changes	18	0.0161	(0.0087,0.0234)	18	0.0161	(0.0087,0.0234)
Delayed Wound Healing	0	0.0000	(0, 0)	0	0.0000	(0, 0)
External Injury Not Related To Breast Implants	5	0.0045	(0.0006,0.0084)	7	0.0078	(0.0016,0.0139)
Extrusion	0	0.0000	(0, 0)	0	0 0000	(0, 0)
Granuloma	1	0.0009	(0,0.0026)	1	0.0009	(0,0.0026)
Hematoma	14	0.0125	(0.006, 0.019)	14	0.0125	(0.006, 0.019)
Implant Malposition/Displacement	1	0.0009	(0,0.0027)	1	0.0009	(0,0.0027)
Infection	8	0.0071	(0.0022, 0.012)	8	0.0071	(0.0022, 0.012)
Inflammation	2	0.0018	(0,0.0042)	2	0.0018	(0,0.0042)
Lactation Difficulties	0	0.0000	(0, 0)	1	0.0012	(0,0.0036)
Lymphadenopathy	1	0.0009	(0,0.0026)	1	0.0009	(0,0 0026)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7 2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Metastatic Disease	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Necrosis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
New Diagnosis of Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Sensation Changes	47	0.0417	(0.03,0.0534)	70	0.0623	(0.0482,0.0764)
Placement Damage	4	0.0035	(0.0001, 0.007)	4	0.0035	(0.0001, 0.007)
Rash	3	0.0027	(0,0.0057)	3	0.0027	(0,0.0057)
Recurrent Breast Cancer	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Seroma	5	0.0044	(0.0006,0.0083)	5	0.0044	(0.0006,0.0083)
Suture Reaction	4	0.0035	(0.0001, 0.007)	4	0.0035	(0.0001, 0.007)
Other	11	0.0098	(0.004,0.0155)	13	0.0116	(0.0053,0.0178)
Abnormal Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsular Contracture Secondary To Radiation Therapy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsule Tear	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Cellulitis	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Distortion Of Breast Shape Not Related To Capsular Contracture	1	0.0009	(0,0.0026)	1	0.0009	(0,0 0026)
Dog Ear Scars From Mastectomy	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Ecchymosis	2	0.0018	(0,0.0042)	2	0.0018	(0,0.0042)
Excessive Implant Movements	2	0.0018	(0,0.0042)	2	0.0018	(0,0.0042)
Explanted Due To Right Side Being Removed	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Extra Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
False Positive For Rupture On Mammogram	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implants Riding High	2	0.0018	(0,0.0042)	2	0.0018	(0,0.0042)
Inframammay Fold Too High	1	0.0010	(0, 0.003)	1	0.0010	(0, 0.003)
Lack Of Projection	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Loss Of Inframammary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Mondor's Disease	3	0.0027	(0,0.0057)	3	0.0027	(0,0.0057)
Muscle Spasm	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Complications	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Unplanned	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Occasional Burning Discomfort Of Skin	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Pain - Sternum And Under Left Arm Intermittent	1	0.0009	(0,0.0026)	1	0.0009	(0,0.0026)
Pt Requests Removal Due To Personal Reasons	2	0.0018	(0,0.0043)	2	0.0018	(0,0.0043)
Siliconoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Soft Mass Left Costal Margin	1	0.0010	(0,0.0029)	1	0 0010	(0,0.0029)
Stitch Abscess	0	0.0000	(0, 0)	1	0.0012	(0,0.0037)
Symmastia	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Symmastia And Implant Malposition	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Tight Benilli Suture	0	0.0000	(0, 0)	0	0.0000	(0, 0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note. Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	131	0.1163	(0.0976, 0.135)	166	0.1477	(0.1269,0.1684)
II. Cosmetic Complication						
Asymmetry	4	0.0036	(0.0001, 0.007)	4	0.0036	(0.0001, 0.007)
Hypertrophic Scarring	22	0.0196	(0.0115,0.0276)	36	0.0321	(0.0218,0.0424)
Ptosis	5	0.0044	(0.0006,0.0083)	5	0.0044	(0.0006,0.0083)
Wrinkling	1	0.0009	(0,0.0026)	3	0.0027	(0,0.0057)
Any Cosmetic Complication	31	0.0275	(0.018,0.0371)	47	0.0419	(0.0301,0.0536)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

	24 Months (a)			36 Months (a)		
Type of Complication or Reoperation	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Any Complication Excluding Cosmetic	195	0.1748	(0.1525,0.1971)	212	0.1947	(0.171,0.2184)
II. Cosmetic Complication						
Asymmetry	4	0.0036	(0.0001, 0.007)	4	0.0036	(0.0001, 0.007)
Hypertrophic Scarring	53	0.0479	(0.0353,0.0605)	53	0.0479	(0.0353,0.0605)
Ptosis	19	0.0177	(0.0098,0.0256)	21	0.0202	(0.0116,0.0288)
Wrinkling	6	0.0054	(0.0011,0.0098)	6	0.0054	(0.0011,0.0098)
Any Cosmetic Complication	79	0.0717	(0.0564,0.0869)	81	0.0741	(0.0586,0.0897)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08.48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side - N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	11	0.0098	(0.004,0.0155)	22	0.0196	(0.0115,0.0277)
Explant with Replacement with Study Device	7	0.0062	(0.0016,0.0108)	14	0.0125	(0.006,0.0189)
Explant without Replacement	4	0.0036	(0.0001, 0.007)	8	0.0072	(0.0022,0.0121)
Other Reoperations	35	0.0311	(0.021,0.0412)	55	0.0490	(0.0364,0.0617)
Biopsy	2	0.0018	(0,0.0042)	3	0.0027	(0,0.0057)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	10	0.0089	(0.0034,0.0144)	18	0.0161	(0.0087,0.0234)
Capsulorrhaphy	3	0.0027	(0,0.0057)	4	0.0036	(0.0001, 0.007)
Capsulotomy	3	0.0027	(0,0.0057)	8	0.0072	(0.0022,0.0121)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Reposition	2	0.0018	(0,0.0042)	2	0.0018	(0,0.0042)
Incision and Drainage	9	0.0080	(0.0028,0.0132)	10	0.0089	(0.0034,0.0144)
Mastopexy	1	0.0009	(0,0.0026)	1	0.0009	(0,0.0026)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
III. Reoperations						
Removal with or without Replacement	34	0.0306	(0.0205,0.0408)	45	0.0437	(0.0311,0.0563)
Explant with Replacement with Study Device	20	0.0179	(0.0101,0.0257)	24	0.0229	(0.0137, 0.032)
Explant without Replacement	14	0.0128	(0.0062,0 0195)	21	0.0211	(0.0121,0.0302)
Other Reoperations	76	0.0683	(0.0535,0.0832)	89	0.0835	(0.0668,0.1003)
Biopsy	5	0.0045	(0.0006,0.0084)	5	0.0045	(0.0006,0.0084)
Breast Mass Excision Dx: Fibroadenoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Capsulectomy	27	0.0243	(0.0153,0.0334)	31	0.0294	(0.0191,0.0397)
Capsulorrhaphy	4	0.0036	(0.0001, 0.007)	4	0.0036	(0.0001, 0.007)
Capsulotomy	14	0.0127	(0.0061,0.0193)	16	0.0150	(0.0077,0.0223)
Create Inframmary Fold	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Excise Breast Mass	1	0.0010	(0,0.0029)	2	0.0022	(0,0.0053)
Excision Of Skin Lesion	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Exploration Right Breast With Evacuation Of Hematoma	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Flap Coverage Of Expander	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Implant Pocket Revision	2	0.0018	(0,0.0044)	2	0.0018	(0,0.0044)
Implant Reposition	4	0.0036	(0.0001,0.0072)	4	0.0036	(0.0001,0.0072)
Incision and Drainage	11	0.0098	(0.004,0.0156)	11	0.0098	(0.004,0.0156)
Mastopexy	3	0.0027	(0,0.0058)	5	0.0049	(0.0006,0.0092)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	6 Months (a)			12 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	0	0.0000	(0, 0)	1	0.0009	(0,0.0027)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	3	0.0027	(0,0.0057)	3	0.0027	(0,0.0057)
Scar Revision	1	0.0009	(0,0.0026)	5	0.0045	(0.0006,0.0084)
Skin Adjustment	3	0.0027	(0,0.0057)	3	0.0027	(0,0.0057)
Any Reoperation	44	0.0390	(0.0277,0.0504)	73	0.0649	(0.0505,0.0793)
Total Implants Assessed	1127	N/A	N/A	1127	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time: 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following. asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3. Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 8.7.2

CUMULATIVE INCIDENCE OF POSTOPERATIVE COMPLICATIONS AND REOPERATIONS (IMPLANT LEVEL)
IMPLANTS USED FOR AUGMENTATION

Type of Complication or Reoperation	24 Months (a)			36 Months (a)		
	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval	Number With Event	Estimated Proportion With Event (b)	Event Confidence Interval
Needle Aspiration	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Nipple Related Procedure (unplanned)	1	0.0009	(0,0.0027)	1	0.0009	(0,0.0027)
Open Incision To Rule Out Implant Rupture	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Removal Of Nodule On Chest Wall	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Breast / External To Pocket	0	0.0000	(0, 0)	0	0.0000	(0, 0)
Revision Of Wound Closure	3	0.0027	(0,0.0057)	3	0.0027	(0,0.0057)
Scar Revision	15	0.0137	(0.0068,0.0205)	18	0.0170	(0.0092,0.0248)
Skin Adjustment	5	0.0045	(0.0006,0.0084)	8	0.0080	(0.0024,0.0136)
Any Reoperation	101	0.0903	(0.0735,0.1071)	117	0.1087	(0.0899,0.1274)
Total Implants Assessed	1127	N/A	N/A	1127	N/A	N/A

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T08_7.SAS Creation Date, Time. 24AUG04 08:48
(a) Time from implant surgery to first occurrence of event.
(b) Based on Kaplan-Meier Estimates.
Note: Excludes planned second stage surgeries.
Note 2: Excludes mild occurrences of the following: asymmetry, breast pain, calcification, implant malposition/displacement, nipple sensation changes, breast sensation changes, nipple complications, and wrinkling.
Note 3: Implant counts exclude events where breast side = N/A.